
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F

(Mark One)

- REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934
OR
- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2023
OR
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
OR
- SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission file number: 001-39081

BioNTech SE

(Exact name of Registrant as specified in its charter)

Federal Republic of Germany
(Jurisdiction of incorporation or organization)

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Securities registered or to be registered, pursuant to Section 12(b) of the Act

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each Representing one ordinary share	BNTX	The Nasdaq Stock Market LLC
Ordinary shares, no par value, with a notional amount attributable to each ordinary share of €1*	—	The Nasdaq Stock Market LLC*

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Securities registered or to be registered pursuant to Section 12(g) of the Act: **None**

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: **None**

Indicate the number of outstanding shares of each of the issuer's classes of capital stock or common stock as of the close of business covered by the annual report.

Ordinary shares, no par value, with a notional amount attributable to each share of €1 outstanding up until March 13, 2024, the most recent practicable date, no par value: 237,725,735

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards † provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP International Financial Reporting Standards as issued by the International Accounting Standards Board Other

If "Other" has been checked in response to the previous question indicate by check mark which financial statement item the registrant has elected to follow. Item 17 Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

* Listed not for trading or quotation purposes, but only in connection with the registration of American Depositary Shares representing such ordinary shares pursuant to the requirements of the Securities and Exchange Commission. The American Depositary Shares are registered under the Securities Act of 1933, as amended, pursuant to a separate registration statement on Form F-6 (File No. 333-233898).

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GENERAL INFORMATION

In this Annual Report on Form 20-F (“Annual Report”), “BioNTech,” the “Group,” the “Company,” “we,” “us,” and “our” refer to BioNTech SE and its consolidated subsidiaries, except where the context otherwise requires.

In response to the fact that our consolidated financial statements are published in Euro, the selected consolidated financial data is presented in Euro as well. Amounts in U.S. dollar are translated into Euro using the exchange rates as per period end or average exchange rates for the periods indicated as published by the German Central Bank (*Deutsche Bundesbank*).

All references in this Annual Report to “\$” mean U.S. dollars and all references to “€” mean Euros.

This Annual Report contains references to our trademarks and to trademarks belong to other entities. Solely for convenience, trademarks and trade names referred to, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Our trademark portfolio includes, but is not limited to, *Comirnaty*, *BioNTainer*, *FixVac*, *RiboCytokine*, *RiboMab*, *Recon* and *Neo-Stim*, including logo versions of some of these trademarks. Brand names appearing in italics throughout this report are trademarks owned by BioNTech. All other trademarks are the property of their respective owners.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements concerning our business, operations and financial performance and condition as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements that are not of historical facts may be deemed to be forward-looking statements. Many of the forward-looking statements contained in this Annual Report can be identified by the use of forward-looking words such as “believes”, “estimates”, “anticipates”, “expects”, “plans”, “intends”, “may”, “could”, “might”, “will”, “should”, “aims” or other similar expressions that convey uncertainty of future events or outcomes.

These forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors that could cause our actual results of operations, financial condition, liquidity, performance, prospects, opportunities, achievements or industry results, as well as those of the markets we serve or intend to serve, to differ materially from those expressed in, or suggested by, these forward-looking statements. These forward-looking statements are based on assumptions regarding our present and future business strategies and the environment in which we expect to operate in the future. Important factors that could cause those differences include, but are not limited to:

- the extent to which COVID-19 vaccines continue to be necessary in the future and any effects of reduced demand for our COVID-19 vaccine, including the write-down of inventory and costs relating to contract manufacturing production capacities that become redundant or unutilized;
- our expected revenues and net profit related to sales of our COVID-19 vaccine (also referred to as *Comirnaty* in the United States and in the European Union to the extent authorized for use), respectively, in territories controlled by our collaboration partners, particularly for those figures that are derived from preliminary estimates provided by our partners;
- our pricing and coverage negotiations for our COVID-19 vaccine with governmental authorities, private health insurers and other third-party payors after our initial sales to national governments;
- competition from other COVID-19 vaccines or related to our other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, safety, side-effect profile and durability of immune response;
- the timing and ability of us and our collaborators to obtain regulatory approval for our COVID-19 vaccine and our product candidates, and to commercialize our approved and investigational product candidates, if approved;
- the pricing and reimbursement of our COVID-19 vaccine and our product candidates, if approved;
- the rate and degree of market acceptance of our COVID-19 vaccine and our product candidates, if approved;
- the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding: the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- our ability to identify research opportunities and discover and develop product candidates;
- the ability and willingness of our third-party collaborators to continue research and development activities relating to our product candidates;
- our expectations regarding the size of the patient populations for our product candidates, if approved for commercial use;
- the impact of COVID-19 on our development programs, supply chain, collaborators and financial performance;
- unforeseen safety issues and claims for personal injury or death arising from the use of our COVID-19 vaccine and other products and product candidates developed or manufactured by us;
- our estimates of our expenses, future revenue and capital requirements and our needs for or ability to obtain additional financing;
- our ability to identify, recruit and retain key personnel;

- our and our collaborators' ability to protect and enforce our intellectual property protection for our proprietary and collaborative product candidates, our ability to protect and defend against potential claims of others' intellectual property, and the scope of such protection;
- the development of and projections relating to our competitors or our industry;
- the amount of and our ability to use net operating losses and research and development credits to offset future taxable income;
- our ability, and that of our collaboration partners, as applicable, to manage development and expansion;
- regulatory developments in the United States and foreign countries;
- our ability to effectively scale our production capabilities and manufacture our products, including our COVID-19 vaccine, and our product candidates;
- our expectations with respect to the timing and amount of any dividends and any potential repurchases of our outstanding ADSs;
- our expectations regarding the timing of customer payments for delivered COVID-19 vaccine;
- our ability to implement, maintain and improve effective internal controls; and
- other factors not known to us at this time.

The preceding list is not intended to be an exhaustive list of all of our forward-looking statements. The forward-looking statements contained in this Annual Report speak only as of the date of this report, and unless otherwise required by law, we do not undertake any obligation to update them in light of new information or future developments or to release publicly any revisions to these statements in order to reflect later events or circumstances or to reflect the occurrence of unanticipated events.

PART I

Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

A. [Reserved]

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Our business is subject to various risks, including those described below. You should consider carefully the risks and uncertainties described below and in our future filings. If any such risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. Additionally, risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and/or prospects.

Risk Factor Summary

- Demand for our COVID-19 vaccine, though difficult to predict, is expected to continue to decrease in the near future. Changing market dynamics will impact our revenue, which currently depends heavily on sales of our COVID-19 vaccine, and result in challenges relating to production of our COVID-19 vaccine.
- Our reported commercial revenue is partially based on preliminary estimates of COVID-19 vaccine sales and costs from Pfizer Inc., or Pfizer, that are likely to change in future periods, which may impact our reported financial results.
- We may be unsuccessful in adapting our COVID-19 vaccine or developing future versions of our COVID-19 vaccine to protect against variants of the SARS-CoV-2 virus and, even if we are successful, a market for vaccines against these variants may not develop.
- Significant adverse events may occur during our clinical trials or even after receiving regulatory approval, which could delay or terminate clinical trials, delay or prevent regulatory approval or market acceptance of any of our product candidates. Since commercialization, we have received, and expect to continue to receive, product liability claims related to our COVID-19 vaccine.
- If we are unable to continue to increase our marketing and sales capabilities on our own or through third parties, we may not be able to market and sell our product candidates effectively in the United States and other jurisdictions, if approved, or generate product sales revenue.
- Other companies or organizations may challenge our intellectual property rights or may assert intellectual property rights that prevent us from developing and commercializing our COVID-19 vaccine or our product candidates and other technologies, or that negatively affect our results of operations.
- Even if we obtain regulatory approval for our product candidates, the products may not gain the market acceptance among physicians, patients, hospitals, treatment centers and others in the medical community necessary for commercial success.

- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict. If our operating results fall below expectations, the price of the ADSs representing our shares could decline.
- If we identify material weaknesses in our internal control over financial reporting and fail to remediate such material weaknesses, we may not be able to report our financial results accurately or to prevent fraud.
- As a “foreign private issuer,” we are exempt from a number of rules under U.S. securities laws, as well as Nasdaq rules, and we are permitted to file less information with the SEC than U.S. companies. This may limit the information available to holders of the ADSs and may make our ordinary shares and the ADSs less attractive to investors.
- Clinical development involves a lengthy and expensive process with an uncertain outcome, and delays can occur for a variety of reasons outside of our control. Clinical trials of our product candidates may be delayed, and certain programs may never advance in the clinic or may be more costly to conduct than we anticipate, any of which can affect our ability to fund our company and would have a material adverse impact on our business.
- mRNA drug development has substantial clinical development and regulatory risks due to limited regulatory experience with mRNA immunotherapies.
- Our approved product and product candidates are based on novel technologies and they may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping. If we or any of the third-party manufacturers we work with encounter such difficulties, our ability to supply materials for clinical trials or any approved product could be delayed or stopped.
- If our efforts to obtain, maintain, protect, defend and/or enforce the intellectual property related to our COVID-19 vaccine or our product candidates and technologies are not adequate, we may not be able to compete effectively in our market.
- We have experienced and may continue to experience significant volatility in the market price of the ADSs representing our ordinary shares.
- Our principal shareholders and management own a significant percentage of our ordinary shares and will be able to exert significant control over matters subject to shareholder approval.

Risks Related to our COVID-19 Vaccine and the Commercialization of our Pipeline

Demand for our COVID-19 vaccine, though difficult to predict, is expected to continue to decrease in the near future. Changing market dynamics will impact our revenue, which currently depends heavily on sales of our COVID-19 vaccine, and result in challenges relating to production of our COVID-19 vaccine.

Prior to the commercialization of our COVID-19 vaccine, we had not sold or marketed any products in our pipeline. As a result, a majority of our total revenues to date are attributable to sales of our COVID-19 vaccine. However, we have experienced and we expect to continue to experience increasing reductions in demand for COVID-19 vaccination generally, including for our vaccine, as the virus becomes endemic and as a growing proportion of the population becomes vaccinated. We expect that future revenues from sales of our COVID-19 vaccine will decrease as demand for vaccination wanes. Such revenues will depend on numerous factors, including:

- the extent to which a COVID-19 vaccine, including any booster shot, continues to be necessary as COVID-19 becomes an endemic virus;
- competition from other COVID-19 vaccines, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response;
- our ability to successfully and timely develop effective vaccines targeting new variants and mutations of COVID-19;
- our ability to receive full regulatory approvals where we currently have emergency use authorizations or equivalents;
- our ability to expand our geographic customer base;

- our pricing and reimbursement negotiations with governmental authorities, private health insurers and other third-party payors after our initial sales to national governments, including the transition towards ordinary-course insurance coverage in the public and private sectors;
- the ability of countries and jurisdictions to store and distribute doses of our COVID-19 vaccine to end users at cold temperatures;
- the safety profile of our COVID-19 vaccine, including if previously unknown undesirable effects or increased incidence or severity of known undesirable effects are identified with our COVID-19 vaccine;
- intellectual property litigation involving our COVID-19 vaccine and COVID-19 vaccines in general; and
- our manufacturing and distribution capabilities for our COVID-19 vaccine.

We cannot accurately predict the revenues our COVID-19 vaccine will generate in future periods or for how long our COVID-19 vaccine will continue to generate material revenues, and we cannot ensure it will maintain its competitive position. Uncertainty in the demand for our COVID-19 vaccine and difficulties in targeting appropriate supply of our COVID-19 vaccines have in the past resulted, and may in the future result, in significant inventory write-downs and cancellations of contract manufacturing orders. Our business and financial condition could be materially affected by lowered COVID-19 vaccine revenues resulting from any of the above factors, or by production and supply chain difficulties. In addition, if our revenues or market share of, or other financial metrics relating to, our COVID-19 vaccine do not meet the expectations of investors or securities analysts, the market price of the ADSs representing our ordinary shares may decline.

Our reported commercial revenue is based on preliminary estimates of COVID-19 vaccine sales and costs from Pfizer that are likely to change in future periods, which may impact our reported financial results.

Our reported commercial revenue is based on preliminary estimates from Pfizer, and other assumptions and judgments that we have made, which may be subject to significant uncertainties. Our commercial revenue includes preliminary estimates in part due to a difference in Pfizer's financial quarter for subsidiaries outside the United States, which consequently creates an additional time lag between the recognition of revenues and the receipt of payment. Although our revenue recognition policy is based on facts and circumstances known to us and various other assumptions that we believe to be reasonable under the circumstances, our actual results may deviate from such reported revenue.

We depend on Pfizer to determine and provide estimates of the costs and profits to be shared with us in the countries where it is commercializing our COVID-19 vaccine under our collaboration agreement with Pfizer for our COVID-19 vaccine, which we refer to as the Pfizer Agreement. Because the information supplied by Pfizer is preliminary and subject to change, the commercial revenue we report based on such information is also subject to finalization. This is particularly true for vaccine sales outside of the United States, where Pfizer has a different reporting cycle than ours. As a result, we may not have the complete sales and costs results outside of the United States for months not covered by the reporting period, but we are nonetheless required to report estimated figures.

Pfizer has historically provided us with profit figures for our COVID-19 vaccine sales in the United States using standard U.S. transfer prices and manufacturing and shipping cost variances (as far as those have been identified) that could be subject to adjustment (e.g., due to changes in manufacturing costs or the price of our COVID-19 vaccine). Pfizer has also provided estimated profits for COVID-19 vaccine sales outside of the United States that were preliminary in nature for the last month of a quarter, as Pfizer's subsidiaries outside of the United States have a different reporting cycle than ours. These estimated figures have changed, and in the future such estimated figures are likely to change, as we receive final data from Pfizer for the applicable period in accordance with the reporting cycle of Pfizer's ex-U.S. subsidiaries and as actual costs become known. Further, to the extent that Pfizer does not provide such preliminary information in the future, our provisional sales figures for territories outside of the United States will be subject to an even greater level of estimate and judgment. Any changes to the preliminary data we report herein may have an impact on our reported revenues and expenses, profitability or financial position.

We may be unsuccessful in adapting our COVID-19 vaccine or developing future versions of our COVID-19 vaccine to protect against variants of the SARS-CoV-2 virus, and even if we are successful, a market for vaccines against these variants may not develop and our ability to continue to generate income from sales of our COVID-19 vaccine is uncertain.

The COVID-19 disease itself is unpredictable and each variant comes with varying levels of transmissibility and severity. Consequently, the burden of the disease may wane or dissipate such that our and other COVID-19 vaccines may be less essential from individual and public health perspectives.

Our COVID-19 vaccine was initially developed based upon the genetic sequence of the original SARS-CoV-2 virus that was first detected. The SARS-CoV-2 virus continues to evolve, and new strains of the virus or those that are already in circulation may prove more transmissible or cause more severe forms of COVID-19 disease than the predominant strains observed to date. Our vaccine may not be as effective in protecting against existing and future variant strains of the SARS-CoV-2 virus as it is against the original virus. While we continue to monitor emerging SARS-CoV-2 strains, undertake investigations into the immunogenicity of our COVID-19 vaccine against new variants as they emerge and develop modified versions of our COVID-19 vaccine against new variants, these efforts may be unsuccessful, and failure to timely and successfully adapt our vaccine to variants of the SARS-CoV-2 virus could lead to significant reputational harm and adversely affect our financial results. It is also possible that we may expend significant resources adapting our COVID-19 vaccine to protect against certain variants of the SARS-CoV-2 virus, but that a market for adapted vaccines does not develop for one or more variants or that demand does not align with our projections or cost expenditures. Moreover, even if we are successful in developing an adapted vaccine and there is a market for the new vaccine, new variants continue to emerge and any adapted vaccine may not be as effective in protecting against such future variant strains.

If we discover safety issues with our products, including our COVID-19 vaccine, that were not known at the time of approval, commercialization efforts for our products could be negatively affected, approved products could lose their approval or sales could be suspended, we could be subject to product liability claims and our business and reputation could be materially harmed.

Our COVID-19 vaccine and any other product candidates for which we receive approval or emergency use authorization are subject to continuing regulatory oversight, including the review of additional safety information. Billions of doses of our COVID-19 vaccination have now been delivered worldwide, and our COVID-19 vaccine is being more widely used by patients as an authorized product than it was used in clinical trials. As a result, undesirable effects and other problems may be observed that were not seen or anticipated, or were not as prevalent or severe, during clinical trials. We cannot provide assurance that newly discovered or developed safety issues will not arise, and we have received, and expect to continue to receive, product liability claims relating to our COVID-19 vaccine. With the use of any vaccine by a wide patient population, serious adverse events may occur from time to time that did not arise in clinical trials or that initially appeared to be unrelated to the vaccine itself and only with the collection of subsequent information were found to be causally related to the product. Safety events that arise outside of a clinical trial setting are difficult to monitor, and given the widespread use of our COVID-19 vaccine, we have experienced difficulty tracking potential treatment-related adverse events on a global basis. Any safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenue and our financial condition. The subsequent discovery of previously unknown problems with a product could negatively affect commercial sales of the product, result in restrictions on the product or lead to the withdrawal of the product from the market. The reporting of adverse safety events involving our products or public speculation about such events could cause the price of the ADSs representing our ordinary shares to decline or experience periods of volatility.

Unexpected safety issues, including any that we have not yet observed in our clinical trials for our COVID-19 vaccine or in real world data, could lead to significant reputational damage for us and our product development platforms going forward and other issues, including delays in our other programs, the need for redesign of our clinical trials and the need for significant additional financial resources.

Failure to comply with continuing regulatory requirements by us or our collaboration partners could adversely impact regulatory approvals for our products, result in product recalls or suspensions, subject us to fines and/or other types of liabilities.

If we or our collaborators fail to comply with applicable continuing regulatory requirements, including good industry practices, such as good manufacturing practices (GMP), we or our collaborators may be subject to fines, suspension or withdrawal of regulatory approvals for specific drugs, product recalls and seizures, operating restrictions and/or criminal prosecutions. We and the manufacturers we engage to make our products and the manufacturing facilities in which our products are made are subject to periodic review and inspection by the U.S. Food and Drug Administration, or the FDA, and other regulatory authorities. If problems are identified during a review or inspection, we or our collaborators may be the subject of adverse regulatory action, including the issuance of untitled or warning letters, which could result in our inability

to use the facility to make our product or a determination that inventories are not safe for commercial sale. Any of these factors could adversely affect our business prospects and our financial position could be materially harmed.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage and adequate reimbursement levels and implement pricing policies favorable to our product candidates. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, and/or delayed payments from government authorities could limit our ability to market those products and decrease our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford certain treatments, including our COVID-19 vaccine and other product candidates we may develop and sell. In addition, because our mRNA product candidates represent an entirely new therapeutic modality, we cannot accurately estimate how future products we may develop and sell would be priced, whether reimbursement could be obtained, or any potential revenue. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment in any of our products. Additionally, even if pricing terms with governmental authorities are agreed upon, there may be delayed or denied payments.

There is significant uncertainty related to the insurance coverage and reimbursement for newly approved products in particular in the United States, including genetic medicines. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel products such as ours. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States but have not been approved for reimbursement in certain European countries.

Outside the United States, certain countries, including a number of member states of the European Union, set prices and reimbursement for pharmaceutical products, with limited participation from the marketing authorization holders. We cannot be sure that such prices and reimbursement will be acceptable to us or our collaborators. If the regulatory authorities in these jurisdictions set prices or reimbursement levels that are not commercially attractive for us or our collaborators, our revenues from sales by us or our collaborators, and the potential profitability of our drug products, in those countries would be negatively affected. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world but have been most drastic in the European Union. Additionally, some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then may experience delays in the reimbursement approval of our product or be subject to price regulations that would delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country.

Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. The Inflation Reduction Act, or IRA, enacted in August 2022 allows the U.S. Department of Health and Human Services, or HHS, to negotiate the price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D. The IRA's negotiation program will apply to high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics), among other negotiation selection criteria. The negotiated prices, which will become effective in 2026 for the first round of selected drugs, will be capped at a statutorily-determined ceiling price. The IRA also penalizes drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, once the out-of-pocket maximum has been reached. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that

fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These IRA provisions will take effect progressively starting in 2023, although the drug negotiation provisions of the IRA are currently the subject of legal challenges. The effects of the IRA on our business and the healthcare industry in general are not yet known. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our products for which we may obtain regulatory approval or the frequency with which any such product is prescribed or used. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importing from other countries and bulk purchasing.

We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products in the marketplace.

Government policies, including relating to manufacturing or export controls, and negative public perception regarding vaccines and mRNA-based therapeutics could severely and adversely impact the manufacturing and sales of our COVID-19 vaccine and other product candidates we may develop, if approved.

There is a heightened risk that vaccines could be subject to export controls, adverse emergency actions or supply requirements by governmental and other authorities. In the past, the European Union and other regions have imposed, or threatened to impose, export controls that would limit or block the delivery of COVID-19 vaccines manufactured in or outside their territories in instances where manufacturers have been delayed or have not fully satisfied their delivery obligations to such governments, which could have prohibited us from delivering our COVID-19 vaccine to other jurisdictions. Vaccines are also at risk of being subject to adverse emergency actions taken by governmental entities in certain countries, including intellectual property expropriation, compulsory licenses, strict price controls or other actions, such as the requirement that specific quantities of vaccine doses be set aside for designated purposes or geographic areas.

Furthermore, public sentiment regarding commercialization of vaccines, the safety and efficacy of our COVID-19 vaccine, other COVID-19 vaccines and treatments, and other public perceptions and misinformation relating to COVID-19, mRNA technology, and our and other COVID-19 vaccines may limit our ability to generate income from sales of our COVID-19 vaccine and other product candidates we may develop and sell, and cause reputational damage.

We face significant competition with other makers of COVID-19 vaccines and may be unable to maintain a competitive market share for our COVID-19 vaccine.

A large number of vaccine manufacturers, academic institutions and other organizations currently have programs to develop COVID-19 vaccine candidates and more than thirty other vaccines have been authorized for emergency use or approved in various countries, including vaccines developed by Moderna, Inc., Johnson & Johnson and University of Oxford/AstraZeneca plc. Our competitors pursuing vaccine candidates may have greater financial, product candidate development, manufacturing and marketing resources than we do. Larger pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for their products, and may have the resources to invest heavily to accelerate discovery and development of their vaccine candidates.

Our efforts to continue successful commercialization of our COVID-19 vaccine may fail if competitors develop and commercialize COVID-19 vaccines that are safer, more effective, produce longer immunity against COVID-19, require fewer administrations, have fewer or less severe undesirable effects, have broader market acceptance, are more convenient to administer or distribute or are less expensive than any vaccine candidate that we have developed or we may develop.

We may not be able to demonstrate sufficient efficacy or safety of our COVID-19 vaccine to obtain permanent regulatory approval in jurisdictions where it has been authorized for emergency use or granted conditional marketing approval.

Our COVID-19 vaccine has been granted full U.S. FDA approval for individuals 12 years and older, emergency or limited use authorization in a number of countries and in the United States for individuals 6 months to 12 years of age and approval for use in certain other countries. Our COVID-19 vaccine has not yet received full approval by regulatory authorities in certain countries where it has been authorized for emergency or temporary use. We and Pfizer intend to continue to observe our COVID-19 vaccine, including vaccine candidates that we may develop for other variants of

COVID-19, in global clinical trials. It is possible that subsequent data from these clinical trials may not be as favorable as data we submitted to regulatory authorities to support our applications for emergency use authorization or marketing or conditional marketing approval or that concerns about the safety of our COVID-19 vaccine will arise from the widespread use of our COVID-19 vaccine outside of clinical trials. Our COVID-19 vaccine may not receive approval outside of the emergency use setting in the countries where it is not currently approved, which could adversely affect our business prospects.

Our COVID-19 vaccine is sensitive to temperature, shipping and storage conditions and could be subject to risk of loss or damage.

Our COVID-19 vaccine is, and other product candidates we develop could be, sensitive to temperature, storage and handling conditions. In particular, while we have improved the required shipping and storage conditions of our COVID-19 vaccine, it must be shipped and stored at cold temperatures. Loss in supply of our COVID-19 vaccine and our product candidates could occur if the product or product intermediates are not stored or handled properly. Shelf life for our product candidates may vary by product, and it is possible that supply of our COVID-19 vaccine or our product candidates could be lost due to expiration prior to use. This has in the past led, and could in the future lead, to additional manufacturing costs and delays in our ability to supply required quantities for clinical trials or for commercial purposes. Such distribution challenges may make our COVID-19 vaccine a less attractive product than other COVID-19 vaccines that do not require as cold storage, and our COVID-19 vaccine may become increasingly less competitive as additional other vaccines become authorized for emergency use. If we, our partners and customers are unable to adequately manage these issues, we may be exposed to product liability claims and the market opportunity for our COVID-19 vaccine may be reduced, each of which could adversely affect our business prospects and materially harm our financial condition.

We are developing other product candidates and services in an environment of rapid technological and scientific change, and our failure to effectively compete would prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do and we may not be able to compete successfully.

The pharmaceutical market is intensely competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and other public and private research organizations are pursuing the development of novel drugs for the same diseases that we are targeting or expect to target. Many of our competitors have:

- greater financial, technical and human resources than we have at every stage of the discovery, development, manufacture and commercialization of products;
- more extensive experience in preclinical testing, conducting clinical trials, obtaining regulatory approvals and manufacturing, marketing and selling drug products;
- product candidates that are based on previously tested or accepted technologies;
- products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

We will continue to face intense competition from products that have already been approved and accepted by the medical community for the treatment of the conditions for which we may develop products in the future. We also expect to face competition from new products that enter the market. There are a number of products currently under development, which may become commercially available in the future, for the treatment of conditions for which we are trying, or may in the future try, to develop drugs. These drugs may be more effective, safer, less expensive, or marketed and sold more effectively than any products we develop.

We anticipate competing with the largest pharmaceutical companies in the world, many of which are currently conducting research in the fields of infectious diseases, immuno-oncology, rare genetic diseases and cancer immunotherapies. Some of these companies have greater financial and human resources than we currently have. In addition to these large pharmaceutical companies, we may directly compete with fully-integrated biopharmaceutical companies and other immunotherapy-focused oncology companies, as well as a number of companies focused on immunotherapies or shared tumor antigen and neoantigen therapeutics, some of which have entered into collaboration and funding agreements with larger pharmaceutical or biotechnology companies.

If we successfully develop other product candidates, and obtain approval for them, we will face competition based on many different factors, including:

- the safety and effectiveness of our products relative to alternative therapies, if any;
- the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration;
- the timing and scope of regulatory approvals for these products;
- the availability and cost of manufacturing, marketing and sales capabilities;
- the price of any approved immunotherapy;
- reimbursement coverage; and
- intellectual property position.

Following our acquisition of InstaDeep Ltd., we also face competition in the rapidly growing and developing artificial intelligence industry. Our competitors may develop or commercialize products and services with significant advantages over any products we develop based on any of the factors listed above or on other factors. In addition, our competitors may develop collaborations with or receive funding from larger pharmaceutical, biotechnology or technology companies, providing them with an advantage over us. Our competitors therefore may be more successful in commercializing their products and services than we are, which could adversely affect our competitive position and business. Competitive products and services may make any products and services we develop obsolete or non-competitive before we can recover the expenses of developing and commercializing such products, if approved, and services.

The market opportunities for some of our product candidates may be small due to the rarity of the disease, or limited to those patients who are ineligible for or have failed prior treatments. As the target patient populations for some of our programs are small, we may be unable to achieve or maintain profitability in future periods without obtaining regulatory approval for additional indications.

The FDA often approves new cancer therapies initially only for use by patients with relapsed or refractory advanced cancer. We expect to seek approval initially for some of our product candidates in this context. Subsequently, for those products that prove to be sufficiently beneficial, we would expect to seek approval in earlier lines of treatment and potentially as a first-line therapy but there is no guarantee that our product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials. We are also developing product candidates for the treatment of rare diseases.

Our projections of the number of people who have or will have the diseases we may be targeting may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of trial participants may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our products, if approved, because the potential target populations may be small, we may be unable to achieve or maintain profitability in future periods without obtaining regulatory approval for additional indications.

If we are unable to continue to increase our marketing and sales capabilities on our own or through third parties, we may not be able to market and sell our product candidates effectively in the United States and other jurisdictions, if approved, or generate sufficient product sales revenue.

We have only relatively recently developed our sales, distribution or marketing capabilities in Germany and Türkiye, and, other than for our COVID-19 vaccine, we have not historically designed our preclinical studies and clinical trials with specific commercialization or marketing considerations in mind. In addition, with respect to our COVID-19 vaccine, we rely heavily on the sales, distribution, and marketing capabilities of our partners, except in Germany and Türkiye. To successfully commercialize any other products that may result from our development programs, several of which are undergoing pivotal clinical trials, we will need to continue developing sales and marketing capabilities in the United States, Europe and other regions, either on our own or with others. We may enter into collaborations with other entities to utilize their mature marketing and distribution capabilities, but we may be unable to enter into marketing agreements on favorable terms, if at all. If our current and future collaborators do not commit sufficient resources to further commercialize our COVID-19 vaccine and our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we may be unable to generate sufficient product sales revenue to sustain our business. We compete with many companies that currently have extensive and well-funded marketing and sales operations. Without continuing to grow our internal team or obtaining the support of third parties to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Our ability to achieve or maintain profitability in future periods depends in part on our and our collaborators' ability to penetrate global markets, where we would be subject to additional regulatory burdens and other risks and uncertainties associated with international operations that could materially adversely affect our business.

Our ability to achieve or maintain profitability in future periods will depend in part on our ability and the ability of our collaborators to commercialize any products that we or our collaborators may develop in markets throughout the world. Commercialization of products in various markets could subject us to risks and uncertainties, including:

- obtaining, on a country-by-country basis, the applicable marketing authorization from the competent regulatory authority;
- the burden of complying with complex and changing regulatory, tax, accounting, labor and other legal requirements in each jurisdiction that we or our collaborators pursue;
- reduced protection for intellectual property rights;
- differing medical practices and customs affecting acceptance in the marketplace;
- import or export licensing requirements;
- governmental controls, trade restrictions or changes in tariffs;
- economic weakness, including inflation, or political instability, particularly in non-U.S. economies and markets;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers;
- foreign currency exchange rate fluctuations;
- the impact of epidemics, pandemics and other public health developments, such as COVID-19, on employees and the global economy;
- reimbursement, pricing and insurance regimes; and
- the interpretation of contractual provisions governed by local laws in the event of a contract dispute.

We do not have prior experience in all of these areas, and the experience we do have in some of these areas is limited. Our collaborators may have limited experience in these areas as well. Failure to successfully navigate these risks and uncertainties may limit or prevent market penetration for any products that we or our collaborators may develop, which would limit their commercial potential and our revenues.

Even if we obtain regulatory approval for our product candidates, the products may not gain the market acceptance among physicians, patients, hospitals, treatment centers and others in the medical community necessary for commercial success.

Even with the requisite approvals, the commercial success of our products will depend in part on the medical community, patients, and third-party or governmental payors accepting immunotherapies in general, and our products in particular, as medically useful, cost-effective and safe.

Any product that we bring to the market may not gain market acceptance by physicians, trial participants, third-party payors, and others in the medical community. Additionally, ethical, social and legal concerns about research involving mRNA could result in additional regulations restricting or prohibiting the products and processes we may use. If these products do not achieve an adequate level of acceptance, we may not generate significant product sales revenue and may not be able to achieve or maintain profitability in future periods. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the potential efficacy and potential advantages over alternative treatments;
- the ability to offer our products, if approved, at competitive prices;
- the prevalence and severity of any undesirable effects, including any limitations or warnings contained in a product's approved labeling;

- the prevalence and severity of any undesirable effects resulting from checkpoint inhibitors or other drugs or therapies with which our products are administered;
- the relative convenience and ease of transportation, storage and administration;
- any restrictions on the use of our products, if approved, together with other medications;
- the willingness of the target patient population to try new therapies, such as mRNA vaccines and therapies, and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage or reimbursement, and patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the products may require significant resources and may never be successful. Our efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors due to the complexity and uniqueness of our programs.

In addition, for our products that are approved for marketing, we and/or our collaborator are subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports for such product, and will need to continue to comply (or ensure that our third-party providers comply) with current good manufacturing practices, or GMP, and current good clinical practices, or GCP, for any clinical trials that we or a collaborator conduct post-approval. In addition, there is always the risk that we or a collaborator or regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any such failure to comply or other issues with our product candidates identified post-approval could have a material adverse impact on our business, financial condition and results of operations.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if approved, profitably.

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid in the United States, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In addition, because certain of our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly

and divert our resources. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, CMS revises the reimbursement systems used to reimburse healthcare providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payors rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payors, and reduce the willingness of physicians to use our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

We intend to seek approval to market our product candidates in the United States, the European Union and other selected jurisdictions. If we obtain approval for our product candidates in any particular jurisdiction, we will be subject to rules and regulations in that jurisdiction. In some countries, particularly those in Europe, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. Some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the marketplace. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

The advancement of healthcare reform legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize any product candidates we or our collaborators develop and may adversely affect the prices for such product candidates.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and promoted a new Medicare Part D coverage gap discount program. Considerable uncertainty remains regarding the implementation and impact of the ACA.

In August 2022, the U.S. Inflation Reduction Act, or the IRA, was enacted, which sets forth meaningful changes to drug product reimbursement by Medicare. The IRA is anticipated to have significant effects on the pharmaceutical industry and may reduce the prices we can charge and reimbursement we can receive for our products in the United States, among other effects. Any reduction in reimbursement from Medicare resulting from the IRA or other legislative or policy changes, or from other government programs may result in a similar reduction in payments from private payers. We cannot be sure whether additional legislative changes will be enacted, or the effect of forthcoming guidance implementing the IRA, or what the impact of such changes on our products and product candidates may be.

The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of

healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to commercialize any products for which we obtain marketing approval.

We expect that additional healthcare reform measures or proposals will be adopted in the future, any of which could limit the amounts that governments will pay for healthcare products and services, which could result in reduced demand for our products and product candidates or additional pricing pressures. In the event that the pricing structures for healthcare products, such as the product candidates we are developing, change materially and limit payments for such product candidates, our business will be adversely impacted as our products may no longer be commercially viable based on their expected net present value; we may have invested significant resources in product candidates that cannot be commercially developed; or we may determine that assets that have reached an early phase of development cannot or will not be taken into further development, notwithstanding their clinical viability. In addition, development assets or clinical programs that are part of our collaborations may no longer be deemed commercially viable to pursue based on our collaborators' assessments of the impact of any proposed, announced, or legislated pricing reforms.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from our approved products and from product candidates that we may successfully develop and for which we may obtain regulatory approval, and may affect our overall financial condition and ability to develop product candidates.

Drug marketing and reimbursement regulations in the European Union and elsewhere may materially affect our ability to market and receive coverage for our products in the member states of the European Union and elsewhere.

Our COVID-19 vaccine is currently approved in the United States, the European Union, and other jurisdictions, and we intend to seek approval to market other product candidates in the United States, the European Union and other selected jurisdictions. If we obtain approval for our products or product candidates in a particular jurisdiction, we will be subject to rules and regulations in that jurisdiction. In some countries, particularly those in the European Union, the pricing of biologics is subject to governmental control and other market regulations that could put pressure on the pricing and usage of our products or product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

In addition, in most countries outside the United States, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and, generally, prices tend to be significantly lower in the European Union. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our collaborators and the potential profitability of any of our product candidates in those countries would be negatively affected.

Risks Related to our Financial Condition and Capital Requirements

Long-term sustainable profitability is difficult to achieve and maintain over time and is highly dependent on various factors.

Our ability to continue to generate revenue and achieve and maintain long-term sustainable profitability depends on our ability, alone or with collaborators, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates. Although we generate revenue from sales of our COVID-19 vaccine and additional limited revenue from other transactions, we expect that future revenues from sales of our COVID-19 vaccine will decrease as demand for vaccination wanes. The amount of long-term revenue from such sales, including the sales of our COVID-19 vaccine, is uncertain at this time. Our ability to generate future revenues from pharmaceutical product sales and sales of our other products and services depends heavily on our success in:

- completing research and preclinical and clinical development of our product candidates;
- seeking and obtaining U.S. and non-U.S. marketing approvals for product candidates for which we complete clinical trials;
- seeking and obtaining market access and favorable pricing terms in the United States, the European Union, and other key geographies;
- furthering the development of our own manufacturing capabilities and manufacturing relationships with third parties in order to provide adequate (in amount and quality) products and services to support clinical development and the market demand for our approved products and product candidates, if approved;
- obtaining market acceptance of our approved products and product candidates as a treatment option;
- launching and commercializing products for which we obtain marketing approval and reimbursement, either through collaborations or, if launched independently, by establishing a sales force, marketing and distribution infrastructure;
- addressing any competing technological and market developments, in particular, declining demand for any of our approved products;
- implementing additional internal systems and infrastructure;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- managing our expenses;
- maintaining, defending, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Additionally, we have incurred significant costs associated with the commercialization of our COVID-19 vaccine. Our expenses could increase beyond our expectations if we are required by the FDA, the European Medicines Agency, or EMA, or other regulatory agencies to perform clinical and other trials or make changes to our manufacturing or quality systems in addition to those that we currently anticipate. Accordingly, such costs could adversely affect our future ability to achieve and maintain profitability.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict. If our operating results fall below expectations, the price of the ADSs representing our ordinary shares could decline.

Our financial condition and operating results have varied in the past and will continue to fluctuate from one financial period to the next due to a variety of factors, many of which are beyond our control.

Factors relating to our business that may contribute to these fluctuations include the following, as well as other factors described elsewhere in this report:

- the size and timing of orders for our COVID-19 vaccine;

- delays or failures in advancement of existing or future product candidates into the clinic or in clinical trials;
- the occurrence of adverse events during our clinical trials or post marketing authorization;
- our ability to develop and manufacture our product candidates and commercialize and manufacture our COVID-19 vaccine at commercial scale;
- our ability to manage our growth and spending;
- our ability to execute our corporate objectives;
- the outcomes of research programs, clinical trials, or other product development or approval processes conducted by us and our collaborators;
- the ability of our collaborators to develop and successfully commercialize products developed from our suite of therapeutic classes;
- our relationships, and any associated exclusivity terms, with collaborators;
- our contractual or other obligations to provide resources to fund our product candidates, and to provide resources to our collaborators or to the collaborations themselves, including take-or-pay or similar obligations;
- the extent to which we repurchase outstanding ADSs under any share repurchase plans we may enter in the future;
- risks associated with the international aspects of our business outside Germany, including the conduct of clinical trials in multiple locations and potential commercialization in such locations;
- our ability to minimize and manage product recalls or inventory losses caused by unforeseen events, cold chain interruption testing difficulties or decreased demand, and our ability to write down certain inventory;
- our ability to report our financial results accurately and in a timely manner;
- our dependence on, and the need to attract and retain, key management and other personnel;
- our ability to obtain, protect, maintain, defend and enforce our intellectual property rights;
- our ability to prevent the theft or infringement, misappropriation or other violation of our intellectual property, trade secrets, know-how or technologies;
- our and our collaborators' ability to defend against claims of infringement of the intellectual property rights of third parties;
- potential advantages that our competitors and potential competitors may have in securing funding, obtaining the rights to critical intellectual property or developing competing technologies or products;
- our ability to obtain additional capital that may be necessary to expand our business;
- our collaborators' ability to obtain and devote additional capital that may be necessary to develop and commercialize products under our collaboration agreements, including our COVID-19 vaccine;
- our ability to minimize and manage product liability claims arising from the use of our COVID-19 vaccine and our product candidates and other future products, if approved;
- business interruptions such as power outages, strikes, acts of terrorism or natural disasters;
- our ability to use our net operating loss carryforwards to offset future taxable income;
- risks of counterparty defaults within our asset management portfolio; and
- increased or unpredictable pricing for the commodities we rely on, including as a result of inflation.

Each of the factors listed above may be affected by the changing impact of COVID-19 on the global community and the global economy.

Due to the various factors mentioned above, and others, the results of any of our periods should not be relied upon as indications of our future operating performance. Our operating results may fluctuate significantly from one reporting period to the next, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

In any particular period, our operating results could be below the expectations of securities analysts or investors, which could cause the price of the ADSs to decline. While as a general matter we intend to periodically report on the status of our product candidate pipeline, including articulating anticipated next steps in the form of development plans or potential data readouts, we may not always be able to provide forward-looking guidance on the timing of those next steps. In addition, we do not control the timing of disclosures of any milestones related to any of our programs that are managed by our collaborators. Any disclosure by a collaborator of data that are perceived as negative, whether or not such data are related to other data that we or others release, may have a material adverse impact on the price of the ADSs or our overall valuation. The price of the ADSs may decline as a result of unexpected clinical trial results in one or more of our programs, including adverse safety events reported for any of our programs.

We have incurred significant losses in the past and we may incur significant losses in the future.

Prior to the first full year of commercialization of our COVID-19 vaccine, we incurred significant losses and negative cash flows from operations due to our significant research and development expenses and our investment in our manufacturing capabilities, and funded our operations primarily from private placements or issuances of ordinary shares (including in the form of ADSs) in connection with our public offerings, generation of proceeds under our collaboration agreements, secured bank loans and issuance of a convertible note.

We have experienced, and we expect to continue to experience, increasing reductions in demand for COVID-19 vaccination generally, including for our vaccine. We expect that future revenues from sales of our COVID-19 vaccine will decrease as demand for vaccination wanes. We plan to continue to invest heavily in research and development as we make a strong drive to build out our global development organization and diversify our therapeutic area footprint. Additionally, we plan to enhance capabilities through complementary acquisitions, technologies, infrastructure and manufacturing. Even for those products for which we have obtained or may obtain regulatory approval or emergency use authorization, our future revenues will depend upon the size of any markets in which such products have received approval or authorization to market, our ability to achieve sufficient market acceptance, reimbursement from third-party payors, and adequate market share in those markets.

If achieved, profitability is difficult to maintain over time and is highly dependent on various factors. Our future financial results will depend, in part, on the rate of our future expenditures, the extent to which we experience long-term success of our commercial products and our ability to obtain funding through revenue from commercial sales, equity or debt financings, sales of assets, collaborations or grants.

As part of our capital allocation strategy, we expect to continue to incur significant and increasing operating expenses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we and our collaborators:

- continue or expand our research or development of our programs in preclinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional preclinical, clinical, or other trials for our product candidates, including under our collaboration agreements;
- continue to invest in our immunotherapy platforms to conduct research to identify novel technologies;
- change or increase our manufacturing capacity or capability;
- change or add additional suppliers;
- add additional infrastructure to our quality control, quality assurance, legal, compliance and other groups to support our operations as a public company and our product development and commercialization efforts, including new and expanded sites globally;
- attract and retain skilled personnel;
- seek marketing approvals and reimbursement for our product candidates;
- develop our sales, marketing, and distribution infrastructure for our COVID-19 vaccine and any other products for which we may obtain marketing approval or emergency use authorization;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;

- acquire other companies;
- make milestone or other payments under any in-license agreements;
- maintain, protect, defend, enforce and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

The amount of, and our ability to use, net operating losses and research and development credits to offset future taxable income may be subject to certain limitations and uncertainty. In addition, pending and future tax audits within our group, disputes with tax authorities and changes in tax law or fiscal regulations could lead to additional tax liabilities. We are subject to routine tax audits by the respective local tax authorities. Any additional tax liability could have an adverse effect on our business, financial conditions, results of operations or prospects.

In Germany, we have unused German tax loss carryforwards for corporate taxes for German group entities with pre tax group losses, though we have not recognized deferred tax assets related to such loss carryforwards for International Financial Reporting Standards, or IFRS, reporting purposes as of December 31, 2023. Deferred tax assets are recognized for unused tax losses only to the extent that it is probable that taxable profit will be available against which the losses can be utilized. In general, net operating loss, or NOL, carryforwards in Germany do not expire. Furthermore, under current German tax laws, certain substantial changes in the Company's ownership and business may further limit the amount of NOL carryforwards that can be used annually to offset future taxable income.

For the German tax group we incurred tax losses up to and including December 31, 2020. Even though we recognized deferred tax assets on a majority of German tax loss carry forwards in 2020 which were fully utilized in 2021, they are, however, subject to review and possible adjustment by the German tax authorities.

In addition, we have U.S. federal and state NOL carryforwards due to our subsidiaries in the United States, which may be subject to limitations on use after an ownership change.

We may not be able to utilize a material portion of our historic or current NOLs or credits in either Germany (resulting from our German tax group or non-tax group entities in Germany) or the United States until these have been finally assessed by the tax authorities or when the limitation period has passed. In addition, the rules regarding the timing of revenue and expense recognition for tax purposes in connection with various transactions are complex and uncertain in many respects, and, if challenged, our recognition may be subject to a revised assessment. In the event any such challenge is sustained, our NOLs could be materially reduced or we could be determined to be a material cash taxpayer for one or more years, which could have an adverse effect on our business, financial conditions, results of operations or prospects.

Furthermore, our ability to use our NOLs or credits is conditioned upon our attaining profitability and generating taxable income. Taxable income exceeding NOLs will be subject to taxation resulting tax liabilities. As described above, we incurred significant net losses in every year since our inception other than 2018, 2021, 2022 and 2023 and anticipate that in the future, we may incur significant losses for some of the group entities. Our ability to utilize our NOL or credit carryforwards in the United States and for some other group entities is uncertain.

Under German tax laws, we are obligated to withhold a percentage of wage tax and social security contributions on personnel expenses if contract services providers are considered to be our internal employees and remit those withholdings to German tax authorities and social security institutions. Late payments may subject us to penalties and fees.

Under German tax and social security laws, we are obligated to withhold a percentage of payments we make to third parties in consideration of the services provided, in case these are considered employment payments, and remit those withholdings to German tax authorities and social security institutions. After a significant volume of service providers were engaged to assist with research, development, manufacturing and supply of our COVID-19 vaccine, we discovered after internal review that we and certain of our subsidiaries did not withhold, report and remit certain German wage taxes and social security contributions in connection with certain contract service providers engaged in a manner comparable to internal employees, which we notified tax authorities about. If we do not properly and timely make required payments in the future, we could be subjected to fees, administrative offenses or other proceedings or penalties.

It is not possible to seek the refund of these wage taxes or social security contributions from either the German tax authorities or social security institutions after filing returns. In Germany, employers are considered secondarily liable for wage taxes.

In addition, value added taxes on invoices received by contract services providers who are considered internal employees are considered non-deductible and must be repaid to the German tax authorities. It is possible to reclaim the VAT repaid to the German tax authorities from the service provider. There is a possibility that the relevant input VAT claims against the contract service providers may, in some instances, not be enforceable as a result of a contract service provider no longer existing, the lapse of time or any other facts preventing the enforcement of such claims.

We may require substantial additional financing to achieve our goals, and a failure to obtain this capital on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

Our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, sales of assets, marketing and distribution arrangements, other collaborations and licensing arrangements, or a combination of these approaches. We may require additional capital to obtain regulatory approval for, and to commercialize, future product candidates. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our spending will vary based on new and ongoing development and corporate activities. Due to the high uncertainty of the length of time and activities associated with discovery and development of our product candidates, we are unable to estimate the actual funds we will require for development, marketing and commercialization activities.

Our future funding requirements, both near and long term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs, and results of preclinical or nonclinical studies and clinical trials for our product candidates;
- the amount and timing of revenues and associated costs from sales of our COVID-19 vaccine;
- the results of research and our other platform activities;
- the clinical development plans we establish for our product candidates;
- the terms of any agreements with our current or future collaborators, and the achievement of any milestone payments under such agreements to be paid to us or our collaborators;
- the terms of any other strategic transactions, including relating to any acquisitions, into which we enter;
- the number and characteristics of product candidates that we develop or may in-license;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable regulatory authorities;
- the cost of filing, prosecuting, obtaining, maintaining, protecting, defending and enforcing our patent claims and other intellectual property rights, including actions for patent and other intellectual property infringement, misappropriation and other violations brought by third parties against us regarding our products or product candidates or actions by us challenging the patent or intellectual property rights of others;
- the effect of competing technological and market developments, including other products that may compete with one or more of our product candidates;
- the cost and timing of completion and further expansion of clinical and commercial scale manufacturing activities sufficient to support all of our current and future programs, including the development of modular production and clinical facilities in various markets via our *BioNTainer* network; and
- the cost of establishing sales, marketing, and distribution capabilities for any product candidates for which we may receive marketing approval and reimbursement in regions where we choose to commercialize our products on our own.

To date, we have financed our operations primarily through the sale of equity securities, revenue from collaborations, and revenue from sales of our COVID-19 vaccine. While we are currently generating product sales and royalty revenue to finance our operations, we cannot be certain that we will continue to generate sufficient revenue from product sales and royalties to finance our operations. If we were to seek financing from outside sources, that additional funding may not be available on favorable terms, or at all. Should our revenues from product sales sufficiently decrease in the future, we expect to finance our future cash needs through a combination of product sales, public or private equity offerings, debt financings, collaborations, licensing arrangements, and other marketing or distribution arrangements. Any fundraising efforts may

divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts, at the right time, on favorable terms, or at all, including as a result of the impact that the shift of COVID-19 towards an endemic phase and other global events, such as political upheavals and economic downturns, may have on the capital markets.

Negative clinical trial data or setbacks, or perceived setbacks, in our programs or with respect to our technology could impair our ability to raise additional financing on favorable terms, or at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders, and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of the ADSs representing our ordinary shares to decline. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that may adversely affect our shareholders' rights.

Further, to the extent that we raise additional capital through the sale of ADSs, ordinary shares or securities convertible or exchangeable into ordinary shares or ADSs, share ownership interests will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to security interests in our assets and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements, sales of assets, collaborations, or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or intellectual property that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts, at the right time, on favorable terms, or at all, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates, or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations, cause the price of the ADSs to decline, and negatively impact our ability to fund operations.

We may encounter difficulties in developing and expanding our company and managing such development and expansion, which could disrupt our operations.

To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational, legal, compliance and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. In addition, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities.

As a growing biotechnology company, we are actively pursuing drug classes, platforms and product candidates in many therapeutic areas and across a wide range of diseases. Successfully developing products for, and fully understanding the regulatory and manufacturing pathways to, all of these therapeutic areas and disease states requires a significant depth of talent, resources and corporate processes in order to allow simultaneous execution across multiple areas. Due to our limited resources, we may not be able to effectively manage this simultaneous execution and the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure and/or give rise to operational mistakes, legal or regulatory compliance failures, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to effectively implement our business strategy. Our future financial performance and our ability to compete effectively and commercialize our COVID-19 vaccine and our product candidates, if approved, will depend in part on our ability to effectively manage the current and future development and expansion of our company.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives. We are subject to financial reporting and other requirements for which our accounting and other management systems and resources may not be adequately prepared. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm the business.

As a public company, we incur significant legal, accounting and other expenses. The U.S. federal securities laws, including the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and rules subsequently implemented by the SEC and

the Nasdaq Stock Market LLC, or Nasdaq, have imposed various requirements on public companies, including requirements to file annual and event-driven reports with respect to our business and financial condition, and to establish and maintain effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations result in substantial legal and financial compliance costs and have made some activities time-consuming and costly. We may not be able to produce reliable financial statements or file these financial statements as part of a periodic report in a timely manner with the SEC or comply with Nasdaq listing requirements. In addition, we could make errors in our financial statements that could require us to restate our financial statements.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting, including the attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To maintain compliance with Section 404, we document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we have needed to continue to dedicate internal resources, have engaged outside consultants, and have adopted a detailed work plan to assess and document the adequacy of internal control over financial reporting. We will continue to implement steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that in the future neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Shareholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives.

If we identify material weaknesses in our internal control over financial reporting and fail to remediate such material weaknesses, we may not be able to report our financial results accurately or to prevent fraud.

Our management is responsible for establishing and maintaining internal control over financial reporting, disclosure controls, and compliance with the other requirements of the Sarbanes-Oxley Act and the rules promulgated by the SEC thereunder. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with international financial reporting standards. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected by the company's internal controls on a timely basis.

Prior to our initial public offering, we identified a material weakness in our internal control which has been fully remediated, but there can be no guarantee that we will not identify additional material weaknesses in the future.

If we are unable to successfully remediate any future material weaknesses or successfully supervise and rely on outside advisors with expertise in these matters to assist us in the preparation of our financial statements, our financial statements could contain material misstatements discovered in the future that could cause us to fail to meet our future reporting obligations and cause the price of the ADSs to decline.

We have various international trade obligations, including customs value calculation, customs tariff number classification and other related securities requirements. Late payments to customs authorities may subject us to penalties and fees.

Our supply chain, production and distribution network across the globe creates an increasing level of complexity in customs and foreign trade processes. The requirements for internal control systems are increasing and must be developed simultaneously. The risk management system for customs and foreign trade, which we are continuously improving, determines which stakeholders, goods, and means of transport should be examined and to what extent. These risks include the potential for non-compliance with customs value calculation, customs tariff number classification, trade restrictions, security regulations as well as the potential failure to facilitate international trade. We have in the past discovered that

certain of our and our subsidiaries' customs value calculations were not applied correctly, following which we notified the customs authorities of potential late payments.

We are, and will likely continue to be, subject to various audits that arise from time to time, including customs and potential future foreign trade audits. If we do not properly address our international trade and customs requirements, we could be subjected to penalties and fees.

As a "foreign private issuer," we are exempt from a number of rules under the U.S. securities laws, as well as Nasdaq rules, and we are permitted to file less information with the SEC than U.S. companies. This may limit the information available to holders of the ADSs and may make our ordinary shares and the ADSs less attractive to investors.

We are a "foreign private issuer," as defined in the rules and regulations of the SEC, and, consequently, we are not subject to all of the disclosure requirements applicable to companies organized within the United States. For example, we are exempt from certain rules under the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act. In addition, our officers and directors are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies. Accordingly, there may be less publicly available information concerning our company than there is for U.S. public companies.

As a foreign private issuer, we file an Annual Report on Form 20-F within four months of the close of each financial year ending December 31 and reports on Form 6-K relating to certain material events promptly after we publicly announce these events. Additionally, we rely on a provision in Nasdaq's Listed Company Manual that allows us to follow German company law and European law applicable to European stock corporations in general, the German Stock Corporation Act (*Aktiengesetz*), the Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE), or the SE Regulation, and the German Act on the Implementation of Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE) (*Gesetz zur Ausführung der Verordnung (EG) NR. 2157/2001 des Rates vom 8. Oktober 2001 über das Statut der Europäischen Gesellschaft (SE)*) (*SE-Ausführungsgesetz-SEAG*), in particular with regard to certain aspects of corporate governance. This allows us to follow certain corporate governance practices that differ in significant respects from the corporate governance requirements applicable to U.S. companies listed on Nasdaq.

For example, we are exempt from regulations of Nasdaq that require a listed U.S. company to:

- have a majority of the board of directors consist of independent directors;
- require non-management directors to meet on a regular basis without management present;
- adopt a code of conduct and promptly disclose any waivers of the code for directors or executive officers that should address certain specified items;
- have an independent compensation committee;
- have an independent nominating committee;
- solicit proxies and provide proxy statements for all shareholder meetings;
- review related party transactions; and
- seek shareholder approval for the implementation of certain equity compensation plans and issuances of ordinary shares.

As a foreign private issuer, we are permitted to follow home country practice in lieu of the above requirements. We therefore continue to follow German corporate governance practices in lieu of the corporate governance requirements of Nasdaq in certain respects. In particular, we follow German corporate governance practices in connection with the distribution of annual and interim reports to shareholders, the application of our code of conduct to our employees and the Supervisory Board, executive remuneration disclosure, proxy solicitation in connection with shareholders' meetings, and obtaining shareholder approval in connection with the establishment of, or material amendment to, certain equity-based compensation plans.

Our audit committee is required to comply with the provisions of Section 301 of the Sarbanes-Oxley Act and Rule 10A-3 of the Exchange Act, both of which are also applicable to U.S. companies listed on Nasdaq. As we are a foreign

private issuer, however, our audit committee is not subject to additional requirements of Nasdaq applicable to listed U.S. companies, including an affirmative determination that all members of the audit committee are “independent,” using more stringent criteria than those applicable to us as a foreign private issuer.

Due to the above exemptions for foreign private issuers, our shareholders will not be afforded the same protections or information generally available to investors holding shares in public companies organized in the United States, some investors may find the ADSs less attractive as a result, and there may be a less active trading market for the ADSs.

We face risks related to catastrophic global events including natural disasters, political crises, or public health epidemics and pandemics and other public health developments, that could adversely affect our operations.

Our business could be adversely impacted by the effects of catastrophic global events including natural disasters such as an earthquake, fire, hurricane, tornado, flood or significant power outage; public health crises such as the COVID-19 pandemic; political crises, such as terrorist attacks, war and other political instability, including the ongoing geopolitical conflicts in the Middle East and in Ukraine, and resulting sanctions imposed by the United States and other countries and retaliatory actions taken by Russia in response to such sanctions; or other catastrophic events.

For example, the ongoing conflict between Russia and Ukraine and the conflicts in the Middle East, and resulting sanctions and other economic actions, have contributed to, and are expected to continue to contribute to, rising prices and shortages of crude oil and natural gas. Prolonged or expanded conflict between Russia and Ukraine and in the Middle East, and political responses to global actions, could further reduce oil and gas supplies, increase energy volatility and have severe adverse effects on regional and global supply chains and economies and our business. Our commercial production of our COVID-19 vaccine is currently run on natural gas, although we believe our production could be powered by alternative fuel sources if needed. Additionally, we continue to evaluate the impacts that a growing or subsequent energy shortage may have on our partners, suppliers and service providers. Were any of these parties to experience significant impacts from this or any other energy shortage, our business could be materially harmed. We cannot predict with certainty the impact a continuing or more severe natural gas shortage would have on our or their operations, including on the manufacturing of our COVID-19 vaccine and the manufacturing and testing of our product candidates.

Although we have generated revenues from sales of our COVID-19 vaccine, there remains uncertainty regarding other potential effects of COVID-19 on our business. For example, if a new variant of COVID-19 emerges for which existing vaccines, including our COVID-19 vaccine, are ineffective, infections may become even more widespread, negatively impact our ability to enroll patients in clinical studies and complete clinical trials on the timelines we currently anticipate, or result in an economic downturn that could affect demand for our products and services or our ability to raise capital, which could have a material adverse effect on our business, operating results and financial condition. Our suppliers, licensors or collaborators could also be disrupted by conditions related to COVID-19 or other pandemics and epidemics, possibly resulting in disruption to our supply chain, clinical trials, partnerships or operations.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter and insurance coverage is becoming increasingly expensive. We do not know if we will be able to maintain existing insurance with adequate levels of coverage, and any liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. We currently maintain insurance coverage for losses relating to property damage, business interruption, transportation, product liability, cyber matters, clinical trials, and several other areas of coverage. We are dedicating resources to exploring additional avenues for more adequate coverage as our business evolves. However, the coverage or coverage limits of our insurance policies may not be adequate. If our losses exceed our insurance coverage, our financial condition would be adversely affected. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources. Clinical trials or regulatory approvals for any of our product candidates could be suspended, which could adversely affect our results of operations and business, including by preventing or limiting the development and commercialization of any product candidates that we or our collaborators may develop.

Additionally, operating as a public company has made it more expensive for us to obtain director and officer liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our Supervisory Board, our Management Board, or our board committees.

Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, such as actual events or concerns involving liquidity, defaults or non-performance, could adversely affect our operations and liquidity.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, a bank which we previously used to support operations in the United States, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver.

While a statement by the U.S. Department of the Treasury, the Federal Reserve and the FDIC stated that all depositors of SVB would have access to all of their money after only one business day following the date of closure and we received such access on March 13, 2023, and neither the amount in question nor any delays in access were material to our operations, uncertainty and liquidity concerns in the broader financial services industry remain. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. The U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to \$25 billion of loans to financial institutions secured by such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments. However, widespread demands for customer withdrawals or other needs of financial institutions for immediate liquidity may exceed the capacity of such program. There is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions in a timely fashion or at all.

While we maintain our cash and cash equivalents in multiple financial institutions worldwide, our access to our cash and cash equivalents in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any material decline in available funding or our ability to access our cash and cash equivalents could adversely impact our ability to meet our operating expenses, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws, any of which could have material adverse impacts on our operations and liquidity.

Risks Related to our Business

Our business is dependent on the successful development, regulatory approval and commercialization of product candidates based on our technology platforms. If we and our collaborators are unable to obtain approval for and effectively commercialize our product candidates for the treatment of patients in their intended indications, our business would be significantly harmed.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain, and we may not be able to obtain approvals for the commercialization of product candidates we may develop. Any product candidates we may develop and the activities associated with their development and commercialization, including design, testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and by comparable global health authorities. To obtain the requisite regulatory approvals to commercialize any of our product candidates, we and our collaborators must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective, including in the target populations. Successful completion of clinical trials is a prerequisite to submitting a biologics license application, or BLA, or a new drug application, or NDA, to the FDA, a Marketing Authorization Application, or MAA, to the EMA, and similar marketing applications to comparable global regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates.

Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. Although our COVID-19 vaccine has received emergency use authorization and/or regulatory approvals in certain countries, it is possible that none of our other product candidates, or any product candidates we may seek to develop in the future, will ever obtain regulatory approval. We have limited experience in filing and supporting the applications necessary to gain marketing approvals and may need to rely on third-party CROs, regulatory consultants or collaborators to assist us in this process. We expect to submit initial BLAs/MAAs for our mRNA-based

product candidates in the United States, the European Union and in other countries globally. In some of these jurisdictions, mRNA-based medicinal products may be classified in different ways and may be subject to specific requirements. Securing regulatory approval requires the submission of extensive quality, preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Benefit and risk are regularly assessed, and any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals in the United States, the European Union and elsewhere, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies and standards of care during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA, EMA and comparable regulatory authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that the data are insufficient for approval and require additional preclinical, clinical or other trials. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Additional delays or non-approval may result if an FDA panel of experts, referred to as an Advisory Committee, or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials, and the review process.

Regulatory agencies also may approve a product candidate for fewer or more limited indications or patient populations than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

The FDA, EMA and other regulatory agencies review the Quality or Chemistry, Manufacturing and Controls, or CMC, section of regulatory filings. Any aspects found unsatisfactory by regulatory agencies may result in delays in clinical trials and commercialization. In addition, the regulatory agencies typically conduct pre-approval inspections at the time of a BLA, MAA or comparable filing. Any findings by regulatory agencies and failure to comply with requirements may lead to delay in approval and failure to commercialize the potential mRNA product candidate.

If we experience delays in obtaining, or if we fail to obtain, approval of any product candidates we may develop, the commercial prospects for those product candidates will be harmed, and our ability to generate revenues will be materially impaired. Additionally, even if we are successful in obtaining marketing approval for product candidates, because our preclinical studies and clinical trials have not been designed with specific commercialization considerations, the commercial prospects for those product candidates could be harmed, and our ability to generate revenues could be materially impaired.

mRNA drug development carries substantial clinical development and regulatory risks due to limited regulatory experience with mRNA immunotherapies.

To our knowledge, other than our and Moderna, Inc.'s COVID-19 vaccines, no mRNA immunotherapies have been approved or received emergency use authorization or conditional marketing authorization to date by the FDA or the EMA. Successful discovery and development of mRNA-based (and other) immunotherapies by either us or our collaborators is highly uncertain and depends on numerous factors, many of which are beyond our or their control. Our product candidates that appear promising in the early phases of development may fail to advance, experience delays in the clinic or clinical holds, or fail to reach the market for many reasons, including:

- discovery efforts aimed at identifying potential immunotherapies may not be successful;
- nonclinical or preclinical study results may show product candidates to be less effective than desired or have harmful or problematic side effects;

- clinical trial results may show the product candidates to be less effective than expected, including a failure to meet one or more endpoints or have unacceptable side effects or toxicities;
- manufacturing or distribution failures or insufficient supply of GMP materials for clinical trials, or higher than expected cost could delay or set back clinical trials, or make our product candidates commercially unattractive;
- our improvements in the manufacturing processes may not be sufficient to satisfy the clinical or commercial demand of our product candidates or regulatory requirements for clinical trials;
- changes that we make to optimize our manufacturing, testing or formulating of GMP materials could impact the safety, tolerability and efficacy of our product candidates;
- pricing or reimbursement issues or other factors could delay clinical trials or make any immunotherapy uneconomical or noncompetitive with other therapies;
- the failure to timely advance our programs or receive the necessary regulatory approvals, or a delay in receiving such approvals, due to, among other reasons, slow or failure to complete enrollment in clinical trials, withdrawal by trial participants from trials, failure to achieve trial endpoints, additional time requirements for data analysis, data integrity issues, BLA, MAA or the equivalent application, discussions with the FDA or the EMA, a regulatory request for additional nonclinical or clinical data, or safety formulation or manufacturing issues may lead to our inability to obtain sufficient funding; and
- the proprietary rights, products and technologies of our competitors may prevent our immunotherapies from being commercialized.

For administrative purposes, mRNA products are classified together with gene therapy products by the FDA. Unlike certain gene therapies that irreversibly alter cell DNA and may cause certain side effects, mRNA is highly unlikely to localize to the nucleus, be reverse transcribed or integrated into the genome. Side effects observed in other gene therapies, however, could negatively impact the perception of immunotherapies despite the differences in mechanism. In addition, the regulatory pathway in the United States and many other jurisdictions for approval is uncertain. Our COVID-19 vaccine is not currently classified as a gene therapy. The regulatory pathway for an individualized therapy, such as our iNeST mRNA-based immunotherapy where each patient receives a different combination of mRNAs, remains undetermined. The number and design of the clinical and preclinical studies required for the approval of these types of medicines have not been established, may be different from those required for advanced medicinal therapy products or therapies that are not individualized or may require safety testing like gene therapy products. Moreover, the length of time necessary to complete clinical trials and submit an application for marketing approval by a regulatory authority varies significantly from one pharmaceutical product to the next and may be difficult to predict.

Our product candidates may not work as intended, may cause undesirable effects or may have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

As with most biological products, use of our product candidates could be associated with undesirable effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. The potential for adverse events is especially acute in the oncology setting, where patients may have advanced disease, have impaired organ function, compromised immune and other systems and may be receiving numerous other therapies. Undesirable side effects or unacceptable toxicities caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EMA or comparable regulatory authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, competent authorities of EU member states, ethics committees, the institutional review boards, or IRBs, at the institutions in which our studies are conducted, or the Data Safety Monitoring Board, or DSMB, could suspend or terminate our clinical trials. The FDA or comparable regulatory authorities could also order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates

could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Monitoring the safety of patients receiving our product candidates is challenging, which could adversely affect our ability to obtain regulatory approval and commercialize our product candidates.

In our ongoing and planned clinical trials, we have contracted, and are expected to continue to contract, with academic medical centers and hospitals experienced in the assessment and management of toxicities arising during clinical trials. Nonetheless, these centers and hospitals may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, inexperience, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA, the EMA or other comparable regulatory authority delaying, suspending or terminating one or more of our clinical trials, and which could jeopardize regulatory approval. The centers using our products, if and when approved, could also have difficulty managing any adverse effects of our products, or use medicines that do not adequately control such undesirable effects or that have a detrimental impact on the efficacy of the treatment.

In addition, even if we successfully advance our product candidates into and through clinical trials, such trials will likely only include a limited number of patients and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate. Further, any clinical trials may not be sufficient to determine the effects and safety consequences of taking our product candidates over a multi-year period.

If any of our product candidates receives marketing approval and we or others later identify undesirable effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues to us, which would materially and adversely affect our results of operations and business. In addition, if one or more of our product candidates or our immunotherapy approach generally prove to be unsafe, our technology platforms and pipeline could be affected, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all and would have an adverse effect on our business.

Much of our pipeline is in preclinical development and these programs could be delayed or not advance into the clinic. Before we can initiate clinical trials for product candidates, we must complete extensive preclinical studies, including IND-enabling Good Laboratory Practice toxicology testing, that support our planned Investigational New Drug applications, or INDs, in the United States or similar applications in other jurisdictions. We must also complete extensive work on CMC activities (including collecting yield, purity and stability data) to be included in the IND filing. CMC activities for a new category of medicines such as mRNA therapies require extensive manufacturing processes and analytical development, which are uncertain and lengthy. For instance, batch failures have occurred as we scale up our manufacturing and may occur in the future. In addition, we have had in the past, and may in the future have, difficulty identifying appropriate buffers and storage conditions to enable sufficient shelf life of batches of our preclinical or clinical

product candidates. If we are required to produce new batches of our product candidates due to insufficient shelf life, it may delay the commencement or completion of preclinical or clinical trials of such product candidates. For example, we cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept the results of our preclinical testing or our proposed clinical programs or if the outcome of our preclinical testing, studies and CMC activities will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and delays can occur for a variety of reasons outside of our control. Clinical trials of our product candidates may be delayed, certain programs may never advance in the clinic or may be more costly to conduct than we anticipate, and we may have difficulty recruiting patients to participate in clinical trials, any of which can affect our ability to fund our company and would have a material adverse impact on our business.

Clinical testing is expensive and complex and can take many years to complete. Its outcome is inherently uncertain. We may not be able to initiate, may experience delays in, or may have to discontinue clinical trials for our product candidates. We and our collaborators also may experience numerous unforeseen events during, or as a result of, any clinical trials that we or our collaborators conduct that could delay or prevent us or our collaborators from successfully developing our product candidates, including:

- the FDA, other regulators, IRBs or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site for any number of reasons, including concerns regarding safety and aspects of the clinical trial design;
- we may experience delays in reaching, or fail to reach, agreement on favorable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we have optimized in the past and may in the future optimize our manufacturing processes, including through changes to the scale and site of manufacturing, which may lead to additional studies (including bridging and bioequivalence studies) or potentially significant changes in our clinical trial designs, requiring additional cost and time, and, as a consequence, lead to a delay in plans for progressing one or more product candidates;
- the outcome of our preclinical studies and our early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results;
- we may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- in an effort to optimize product features, we have made in the past and may continue to make changes to our product candidates after we commence clinical trials of a medicine which may require us to repeat earlier stages of clinical testing or delay later-stage testing of the medicine;
- clinical trials of any product candidates may fail to show safety or efficacy, or may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials, or we may decide to abandon product development programs;
- differences in trial design between early-stage clinical trials and later-stage clinical trials may make it difficult to extrapolate the results of earlier clinical trials to later clinical trials;
- preclinical and clinical data are often susceptible to varying interpretations and analyses, and many product candidates believed to have performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval;
- our product candidates may have undesirable effects or other unexpected characteristics. One or more of such effects or events could cause regulators to impose a clinical hold on the applicable trial, or cause us or our investigators, IRBs or ethics committees to suspend or terminate the trial of that product candidate or any other of our product candidates for which a clinical trial may be ongoing;
- the number of trial participants required for clinical trials of any product candidates may be larger than we anticipate, identification of trial participants for such trials may be limited, enrollment in these clinical trials may

be slower than we anticipate due to perceived adverse effects, limited patient populations, competitive trials, risks related to COVID-19 or other reasons, or participants may withdraw from clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;

- despite robust sponsor oversight, our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or withdraw from the trial, which may require that we add new clinical trial sites;
- regulators may elect to impose a clinical hold, or we, our investigators, IRBs or ethics committees may elect to suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to an unacceptable benefit-risk ratio;
- with respect to infectious disease vaccine trials in particular, we have to wait for particular level of infection in the placebo arm in order to assess protection provided by vaccine, and we cannot control the rate of exposure or infection which can make timing uncertain;
- the cost of preclinical or nonclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate;
- safety or efficacy concerns regarding our product candidates may result from any concerns arising from nonclinical or clinical testing of other therapies targeting a similar disease state or other therapies, such as gene therapy, that are perceived as similar to ours; and
- the FDA or other regulatory authorities may require us to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

We could also encounter delays if a clinical trial is suspended or terminated by us, the FDA or other regulatory authorities, ethics committees, or the IRBs of the institutions in which such trials are being conducted, or if such trial is recommended for suspension or termination by the DSMB. We may in the future be delayed in gaining clearance from the FDA or other regulators to initiate clinical trials through, among other things, the imposition of a clinical hold in order to address comments from such regulators on our clinical trial design or other elements of our clinical trials. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols; inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold; unforeseen safety issues or adverse side effects; failure to demonstrate a benefit, or adequate benefit-risk ratio, from using a product candidate; failure to establish or achieve clinically meaningful trial endpoints; changes in governmental regulations or administrative actions; or lack of adequate funding to continue the clinical trial. Many of the factors that cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. We could also experience delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. We must also complete extensive work on CMC activities that require extensive manufacturing processes and analytical development, which are uncertain and lengthy.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA and regulatory authorities in other jurisdictions have limited experience with commercial development of several of our technologies. The FDA may require an Advisory Committee to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials, as the FDA often adheres to the Advisory Committee's recommendations. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be certain.

Moreover, the FDA and other regulatory authorities have indicated that, prior to commencing later stage clinical trials for our mRNA-based product candidates, we will need to scale up and further refine assays to measure and predict the potency of a given dose of these product candidates. Any delay in the scaling and refining of assays that are acceptable to the FDA or other regulatory authorities could delay the start of future clinical trials. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data for our clinical trials or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Significant additional preclinical or nonclinical testing and studies or clinical trial delays for our product candidates also could allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in the development of our product candidates may harm our business, financial condition and prospects significantly.

If we or our collaborators encounter difficulties enrolling participants in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We depend on enrollment of participants in our clinical trials for our product candidates. In the past, our collaborators have found, and we or our collaborators may in the future find, it difficult to enroll trial participants in our clinical studies, which could delay or prevent clinical studies of our product candidates. Identifying and qualifying trial participants to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies depends on the speed at which we can recruit trial participants to participate in testing our product candidates. Delays in enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. If trial participants are unwilling to participate in our studies because of negative publicity from adverse events in our trials or other trials of similar products, or those related to specific a therapeutic area, or for other reasons, including competitive clinical studies for similar patient populations, the timeline for recruiting trial participants, conducting studies, and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our product, or termination of the clinical studies altogether.

We may not be able to identify, recruit and enroll a sufficient number of trial participants, or those with required or desired characteristics to achieve diversity in a study, to complete our clinical trials in a timely manner. Patient and subject enrollment is affected by factors including:

- severity of the disease under investigation;
- complexity and design of the study protocol;
- size of the patient population;
- eligibility criteria for the study in question;
- proximity and availability of clinical study sites for prospective trial participants;
- availability of competing therapies and clinical trials, including between our own clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to monitor trial participants adequately during and after treatment;
- ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and trial participants' perceptions of the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- our ability to obtain and maintain participant informed consent;
- major changes in the approval status of competitor investigational products during the clinical trial period;
- impacts related to the spread of COVID-19; and
- the risk that trial participants enrolled in clinical trials will not complete a clinical trial.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of trial participants available to us because some trial participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by a third party. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of trial participants who are available for our clinical trials at such clinical trial sites. Moreover, because in some cases our product candidates represent a therapeutic novelty in contrast to more traditional methods for disease treatment and

prevention, potential trial participants and their doctors may be inclined to use conventional therapies or other investigational therapies rather than enroll trial participants in any future clinical trial involving more novel product candidates. Additionally, if new product candidates, such as gene editing therapies, show encouraging results, potential trial participants and their doctors may be inclined to enroll trial participants in clinical trials using those product candidates. If such new product candidates show discouraging results or other adverse safety indications, potential trial participants and their doctors may be less inclined to enroll trial participants in our clinical trials.

In particular, certain conditions for which we plan to evaluate our current product candidates are rare diseases with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials will further limit the pool of available trial participants. Additionally, the process of finding and diagnosing patients may prove costly. Each of the foregoing risks may continue to be affected by the spread of seasonal viral infections, including COVID-19, as well as the potential for any new pandemic caused by an as-yet-unknown agent.

A variety of risks associated with conducting research and clinical trials abroad and marketing our product candidates internationally could materially adversely affect our business.

Clinical trials of our product candidates are currently being conducted in several countries, and we plan to commercialize our product candidates, if approved, globally. Accordingly, we are subject to additional risks related to operating in multiple countries, including:

- differing regulatory requirements in such countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- increased difficulties in managing the logistics and transportation of storing and shipping product candidates produced in Germany and shipping the product candidate to the patient abroad;
- import and export requirements and restrictions;
- restrictions on transfers of information, including certain technologies and personal data;
- economic weakness, including inflation, or political instability in particular economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- taxes, including withholding of payroll taxes;
- currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing operations outside of Germany;
- workforce uncertainty in countries where labor unrest is more common;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977 or comparable regulations in other jurisdictions;
- challenges enforcing our contractual and intellectual property rights, especially in those countries that do not respect and protect intellectual property rights to the same extent as Germany and the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or public health epidemics or pandemics.

The extent to which the COVID-19 virus continues to impact our operations, including our clinical trial operations, as it becomes endemic will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including new outbreaks, new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. In the future, similar events could affect our ability to manufacture and commercialize our product candidates.

In addition, we and our partners have conducted and are expecting in the future to conduct clinical trials for our product candidates at clinical sites located outside of the United States. Although the FDA may accept data from clinical trials outside the United States that are not conducted under an IND, acceptance of this data in support of a marketing

application or IND requires the clinical trial to have been conducted in accordance with GCPs, and that FDA is able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. Where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are considered applicable to the U.S. patient population and U.S. medical practice, the clinical trials were performed by clinical investigators of recognized competence, and the data is considered valid without the need for an onsite inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an onsite inspection or other appropriate means. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States in support of a marketing application. If the FDA does not accept data from our clinical trials of our product candidates, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our development of a product candidate.

These and other risks associated with our international operations and our collaborations with our collaborators may materially adversely affect our ability to attain or maintain profitable operations.

Interim top-line and preliminary data from studies or trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim top-line or preliminary data from preclinical studies or clinical trials. Interim data are subject to the risk that one or more of the outcomes may materially change as more data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Additionally, interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to disclose publicly regarding a particular study or clinical trial is based on what is typically extensive information, and our securityholders may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by our securityholders or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the top-line data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business prospects.

Results of earlier studies and trials of our product candidates may not be predictive of future trial results.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Notwithstanding any potential promising results in earlier studies and trials, we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates. In addition, the results of our preclinical studies may not be predictive of the results of outcomes in human clinical trials. For example, our tumor-specific cancer immunotherapy candidates and any future product candidates may demonstrate different chemical, biological and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways. Product candidates in later stages of clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies and initial

clinical trials. Even if we are able to initiate and complete clinical trials, the results may not be sufficient to obtain regulatory approval for our product candidates.

Our planned clinical trials or those of our collaborators may be less efficacious or may reveal significant adverse events not seen in our preclinical or nonclinical studies and may result in a safety profile that could delay or terminate clinical trials, or delay or prevent regulatory approval or market acceptance of any of our product candidates.

There is typically an extremely high rate of attrition for product candidates across categories of medicines proceeding through clinical trials.

These product candidates may fail to show the desired safety and efficacy profile in later stages of clinical trials despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates.

Many of our product candidates are being developed or are intended to be co-administered with other developmental therapies or approved medicines. For example, autogene cevumeran (BNT122) is being developed to be co-administered with checkpoint inhibitors. Such combinations may have additional side effects, which may be difficult to predict in future clinical trials.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting trial participants to any of our clinical trials, trial participants may withdraw from trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. We, the FDA or other regulatory authorities, ethics committees or an IRB may impose a clinical hold on, or suspend or terminate, clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, an unfavorable benefit-risk ratio may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

If we are not successful in discovering, developing and commercializing additional product candidates beyond our current portfolio, our ability to expand our business and achieve our strategic objectives would be impaired.

Although a substantial amount of our efforts focus on the clinical trials and potential approval of our existing product candidates, a key element of our strategy is to discover, develop and potentially commercialize additional products beyond our current portfolio to treat various conditions and in a variety of therapeutic areas. We intend to do so by investing in our own drug and target discovery efforts, exploring potential collaborations for the development of new products, and in-licensing technologies. Identifying new product candidates requires substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Even if we identify product candidates that initially show promise, we may fail to develop and commercialize such products successfully for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- an approved product may not be accepted as safe and effective by trial participants, the medical community or third-party payors.

If we are unsuccessful in identifying and developing additional products, our potential for growth may be impaired.

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified senior management and scientific personnel.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent upon members of our management and scientific teams. We may not be able to retain these persons due to the competitive environment in the biotechnology industry, as well as a current global shortage of these highly qualified individuals. The loss of any of these persons' services may adversely impact the achievement of our research, development, financing and commercialization objectives. We are also aware of physical threats made against certain of these people. In response to these threats, we have deployed personal protection for such employees and increased our security generally. We currently do not have "key person" insurance on any of our employees.

In addition, we rely on consultants, contractors and advisors, including scientific and clinical advisors, to assist us in formulating our research and development, regulatory approval and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The loss of the services of one or more of our current employees or advisors might impede the achievement of our research, development, regulatory approval and commercialization objectives. In addition, we have flexibly grown our workforce through the use of contractors and part-time workers. We may not be able to retain the services of such personnel, which might result in delays in the operation of our business.

Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will be critical to our success as well. Competition for skilled personnel, including in mRNA research, clinical development, clinical operations, regulatory affairs, therapeutic area management and manufacturing, is intense and the turnover rate can be high. We may not be able to attract and retain personnel on favorable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for individuals with similar skill sets. In addition, adverse publicity, and the failure to succeed in preclinical studies or clinical trials or in applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse impact on our business, financial condition, results of operations and prospects.

Our employees, principal investigators and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could have an adverse effect on the results of our operations.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators and consultants, despite our robust efforts to prevent such misconduct through sponsor oversight. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, to provide accurate information to the FDA, the EMA and other regulatory authorities, to comply with healthcare fraud and abuse laws and regulations in the United States and abroad, to report financial information or data accurately or to disclose unauthorized activities to us. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

Employment-related disputes, including employee litigation and unfavorable publicity, could negatively affect our future business.

From time to time we may be subject to claims by our employees or regulatory authorities with respect to employment and workplace matters, including lawsuits or proceedings against us regarding injury, creating a hostile work place, discrimination, wage and hour disputes, sexual harassment or other employment issues. In recent years, there has been an increase in the number of discrimination and harassment claims generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these claims have had a significant negative impact on some businesses. Certain companies that have faced employment- or harassment- related lawsuits have

had to terminate management or other key personnel, and have suffered reputational harm that has negatively impacted their business. If we were to face any employment-related claims, our business could be negatively affected.

The illegal distribution and sale by third parties of counterfeit versions of our COVID-19 vaccine, or, if approved, our other product candidates, could have a negative impact on our financial performance or reputation.

Third parties have in the past and may continue to illegally distribute and sell counterfeit versions of COVID-19 vaccines. Counterfeit products are frequently unsafe or ineffective, and may even be life-threatening. Counterfeit medicines may contain harmful substances or the wrong dosage. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version.

Reports of adverse reactions to counterfeit products, increased levels of counterfeiting, or unsafe vaccines could materially affect public confidence in our COVID-19 vaccine or other product candidates. It is possible that adverse events caused by unsafe counterfeit vaccines will mistakenly be attributed to our COVID-19 vaccine, or, if approved, our other product candidates. In addition, thefts of inventory at warehouses, plants or while in-transit, which are subsequently improperly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation, and our business. Public loss of confidence in the integrity of our COVID-19 vaccine or, if approved, our other product candidates, as a result of counterfeiting or theft could have a material adverse effect on our business, results of operations, and financial condition.

We and our collaborators or other contractors or consultants depend on information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.

Our internal computer systems and those of our current and any future collaborators, vendors, and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, cybersecurity threats, war, and telecommunication and electrical failures. If any such material system failure, accident or security breach were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from one or more ongoing or completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, because of our approach of running multiple clinical trials in parallel, any breach of our computer systems may result in a loss of data or compromised data integrity across many of our programs in many stages of development. Any such breach, loss or compromise of clinical trial participant personal data may also subject us to civil fines and penalties, including under the EU General Data Protection Regulation, or the GDPR, relevant law of an EU member state, HIPAA, and other relevant state and federal privacy laws in the United States or in other jurisdictions. To the extent that any disruption or security breach were to result in a loss of, or damage to, data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed.

While we have not experienced any material system failures, accidents or security breaches to date, in December 2020, we were informed by the EMA that the agency was subject to a cyberattack and that some documents relating to our regulatory submission for our COVID-19 vaccine candidate, which was stored on an EMA server, had been unlawfully accessed. None of our systems were breached in connection with this incident and we are unaware that any study participants were identified through the data being accessed.

We have put systems and procedures in place to minimize the likelihood of such incidents reoccurring; however, we cannot guarantee that third parties will not be able to gain unauthorized access to or otherwise breach our systems in the future. Any such unauthorized access or breach could adversely affect our business, results of operations and financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of our current or future product candidates.

We face an inherent risk of product liability exposure related to the testing of any of our current or future product candidates in clinical trials, and an even greater risk related to any commercialized products, such as our COVID-19 vaccine. We have received product liability claims against our COVID-19 vaccine, and expect to receive additional product liability claims in the future. If we cannot successfully defend ourselves against claims that our products and/or our product

candidates have caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product or product candidate that we may develop;
- loss of revenue;
- substantial monetary awards to patients, healthy volunteers or their children;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;
- the inability to commercialize any products or product candidates that we may develop; and
- injury to our reputation and significant negative media attention.

We carry clinical trial insurance and product liability insurance, which we believe to be sufficient in light of our current clinical programs and commercial operations; however, the amount of coverage we have obtained may not be adequate and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause the price of the ADSs to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

If our products become subject to a product recall it could harm our reputation, business and financial results.

The FDA and similar governmental authorities in other jurisdictions have the authority to require the recall of certain commercialized products. In the case of the FDA, the authority to require a recall of a biologic product must be based on an FDA finding that a batch, lot or other quantity of the biologic product presents an imminent or substantial hazard to the public health. In addition, some governmental bodies outside the United States have the authority to require the recall of any product or product candidate in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us could occur as a result of manufacturing errors, design or labeling defects or other deficiencies and issues.

Recalls of any of our products or, if approved, our product candidates, would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. A recall announcement could harm our reputation with customers and negatively affect our sales, if any.

Issues in the development and use of AI, combined with an uncertain regulatory environment, may result in reputational harm, liability or other adverse consequences to our business.

We are investing in AI technology systems, including through our acquisition of InstaDeep, and such systems are complex and rapidly changing. We face significant competition from other companies with respect to our AI and machine learning services, along with an evolving regulatory landscape. The introduction of AI into the development and manufacturing of our product candidates, or the provision of services relating to AI technologies and applications, may result in new or enhanced governmental or regulatory scrutiny, litigation, intellectual property risks, confidentiality or security risks, ethical concerns or other complications that could harm our business, reputation or financial condition.

Uncertainty around AI may require additional investment in the development and maintenance of proprietary datasets and development of appropriate protections and safeguards for handling the use of customer data with AI technologies, which may be costly and could impact our expenses. In addition, AI may create content that appears correct but is inaccurate or flawed, and if created by third parties, may be mistakenly attributed to us. Our customers or others may rely on or use this flawed content to their detriment, which may expose us to brand or reputational harm, competitive harm or legal liability.

Our ability to effectively monitor and respond to the rapid and ongoing developments and expectations relating to environmental, social and governance, or ESG, matters, including related social expectations and concerns, may impose unexpected costs or result in reputational or other harm that could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the price of ADSs representing our ordinary shares to decline.

There are rapid and ongoing developments and changing expectations relating to ESG matters and factors such as the impact of our operations on the environment, access to our COVID-19 vaccine, corporate governance, our practices relating to product stewardship, management of business ethics, human rights diligence in our own operations and our supply chain, and human resource development, which may result in increased regulatory, social or other scrutiny on us.

We believe we must address climate risks due to our own contribution to climate change (inside-out perspective), risks due to physical effects of climate change as well as transition risks (outside-in perspective), and interactions between both perspectives. To this end, we have set ourselves near-term science-based emissions reduction targets for our own operations (scope 1, 2) and for our supply chain (supplier engagement target for scope 3), validated by the Science Based Targets initiative (SBTi) in early February 2024.

Additionally, we are addressing increasingly complex regulatory requirements with respect to human rights risks, including German legislation (for example, the Act on Corporate Due Diligence Obligations for the Prevention of Human Rights Violations in Supply Chains (“Lieferkettensorgfaltspflichtengesetz - LkSG”), potential legislative planning by the European Union and local or regional regulations. We are expected by regulation to identify, prevent, mitigate and ideally end the extent of any potential adverse impacts or violations throughout our own operations and value chain.

Finally, we are faced with increasing ESG related transparency and reporting obligations. These requirements arise, for example, from the EU CSRD regulation and the ESRS sustainability standards, from specific human right reporting regulations (e.g. section 10 of the German LkSG), the recently-announced SEC rules that will require registrants to provide additional climate-related disclosures in future periods, and other possible obligations.

Should we fail to meet our climate protection targets or if we are unable to adequately recognize and respond to such developments and governmental, societal, investor and NGO expectations relating to such ESG matters, we may have to pay substantial fines, forego corporate opportunities, become subject to additional scrutiny, incur unexpected costs or experience damage to our reputation or our various brands. If any of these events were to occur, there may be a material adverse effect on our business, financial condition, cash flows and results of operations, and the price of ADSs representing our ordinary shares may decline.

We have observed that in addition to the importance of their financial performance, companies are increasingly being judged by their performance on ESG matters. A variety of organizations measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. We may fail to comply with standards or best practices put forth by such organizations or by governmental or regulatory bodies. In addition, investment in funds that specialize in companies that perform well in such assessments are increasingly popular, and major institutional investors have publicly emphasized the importance of such ESG measures to their investment decisions. In light of investors’ increased focus on ESG matters, there can be no certainty that we will manage such issues successfully, or that we will successfully meet society’s expectations as to our proper role. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, the price of ADSs representing our ordinary shares, financial condition, or results of operations, including the sustainability of our business over time.

Risks Related to the Manufacturing of our COVID-19 Vaccine, our Product Candidates and Future Pipeline

Our COVID-19 vaccine and product candidates are based on novel technologies and they may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping. If we or any of the third-party manufacturers we work with encounter such difficulties, our ability to supply materials for clinical trials or any approved product could be delayed or stopped.

The manufacturing processes for our COVID-19 vaccine and our product candidates are novel and complex. Due to the novel nature of this technology and the recency of our experience at larger scale production, we may encounter difficulties in manufacturing, product release, shelf life, testing, storage and supply chain management, or shipping. These difficulties could be due to any number of reasons, including, but not limited to, complexities of producing batches at larger scale, equipment failure, choice and quality of raw materials and excipients, analytical testing technology, and product instability. In an effort to optimize product features, we have in the past and may in the future make changes to our product candidates in their manufacturing and stability formulation and conditions. This has resulted in the past, and may in the future result, in our having to resupply batches for preclinical, clinical, or commercial activities when there is insufficient product stability during storage and insufficient supply. Insufficient stability or shelf life of our products or product candidates could materially delay our or our collaborators’ ability to continue the clinical trial for that product candidate or require us to begin a new clinical trial with a newly formulated drug product, due to the need to manufacture additional preclinical, clinical or commercial supply.

For example, in March 2021 we received product quality complaints related to our COVID-19 vaccine in Hong Kong. A thorough investigation into these complaints concluded that the reported product quality complaints were due to the combination of a deficient container closure process, or crimping, at one specific contract manufacturing organization when such containers were later shipped at ultra-cold conditions created by shipping on dry ice. The investigation did not identify any safety issues related to the product quality complaints. We and our COVID-19 vaccine collaboration partner in Hong Kong, Fosun Pharma, subsequently supplied replacement COVID-19 vaccine vials, but we cannot assure you that we will not experience similar product quality complaints in the future.

Our rate of innovation is high, which has resulted in, and will continue to cause a high degree of, technology change that can negatively impact product comparability during and after clinical development. Furthermore, technology changes may drive the need for changes in, modification to, or the sourcing of, new manufacturing infrastructure or may adversely affect third-party relationships.

The process to generate mRNA medicines is complex and, if not developed and manufactured under well-controlled conditions, can adversely impact pharmacological activity. We may encounter difficulties in scaling up our manufacturing process, thereby potentially impacting clinical and commercial supply. Additionally, for individualized therapies, we may encounter issues with our ability to timely and efficiently manufacture product given the on-demand requirements of such therapies, thereby potentially impacting clinical and commercial supply.

As we continue developing new manufacturing processes for our drug substance and drug product, the changes we implement to the manufacturing process may impact, in turn, specification and stability of the drug product. Changes in our manufacturing processes may lead to failure of lots and this could lead to a substantial delay in our clinical trials or an inability to supply sufficient commercial quantities of drug product. Our mRNA product candidates may prove to have a stability profile that leads to an unfavorable shelf life. This poses risk in supply requirements, wasted stock and higher cost of goods.

We are dependent on a number of equipment providers who are also implementing novel technology. Further, we have developed our own custom manufacturing equipment for certain of our product candidates. If such equipment malfunctions or we encounter unexpected performance issues, we could encounter delays or interruptions to clinical and commercial supply.

Due to the number of different programs, we may in the future have cross contamination of products inside of our factories, CROs, external contract manufacturing organizations, or CMOs, suppliers or in the clinic that affect the integrity of our products. Additionally, for some programs the manufacturing scale is extremely small compared to the standard volumes of supply, such that we run the risk of contaminating the process each time we reopen a container to use remaining supplies.

As we scale the manufacturing output for particular programs, we plan to continuously improve yield, purity and the pharmaceutical properties of our product candidates from IND-enabling studies through commercial launch, including shelf life stability and solubility properties of drug product and drug substance. Due to continuous improvement in manufacturing processes, we may switch processes for a particular program during development. However, after the change in process, more time is required for pharmaceutical property testing, such as six- or 12- month stability testing. That may require resupplying clinical or commercial material, or making additional GMP batches to keep up with clinical trial demand before such pharmaceutical property testing is completed.

We are utilizing a number of raw materials and excipients that are either new to the pharmaceutical industry or are being employed in a novel manner. Some of these raw materials and excipients have not been scaled to a level to support commercial supply and could experience unexpected manufacturing or testing failures, or supply shortages. Such issues with raw materials and excipients could cause delays or interruptions to clinical and commercial supply of our COVID-19 vaccine and our product candidates. Further, now and in the future, one or more of our programs may have a single source of supply for raw materials and excipients. Some of our suppliers are located in countries different from our manufacturing sites. Export restrictions could lead to unplanned interruptions in manufacturing and thus impacting supply of both clinical and commercial material.

We have established a number of analytical assays, and may have to establish several more, to assess the quality of our mRNA products and product candidates. We may identify gaps in our analytical testing strategy that might prevent release of product or could require product withdrawal or recall. For example, we may discover new impurities that have an impact on product safety, efficacy or stability. This may lead to an inability to release mRNA products or product candidates until the manufacturing or testing process is rectified.

Our product and product intermediates are extremely temperature sensitive, and we may learn that any or all of our products are less stable than desired. We may also find that transportation conditions negatively impact product quality. This may require changes to the formulation or manufacturing process for one or more of our products or product candidates and result in delays or interruptions to clinical or commercial supply. In addition, the cost associated with such transportation services and the limited pool of vendors may also add additional risks of supply disruptions. As we are transporting intermediate products with holding times in refrigeration (TIR) and allowed times out of refrigeration (TOR) across long distances and crossing borders, traffic issues and customs delays could lead to the loss of batches which would need to be replaced.

Certain of our product candidates are uniquely manufactured for each patient and we may encounter difficulties in production, particularly with respect to scaling our manufacturing capabilities. If we or any of the third-party manufacturers with whom we contract encounter these types of difficulties, our ability to provide such product candidates for clinical trials or, if approved, products for patients could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

We custom design and manufacture certain product candidates that are unique and tailored specifically for each patient. Manufacturing unique lots of these product candidates is susceptible to product loss or failure due to issues with:

- logistics associated with the collection of a patient’s tumor, blood or other tissue sample;
- shipping such samples to a facility for genetic sequencing;
- next-generation sequencing of the tumor mRNA;
- biopsy of a sufficient quantity of cancerous tissue to allow for proper sequencing and identification of tumor-specific mutations;
- identification of appropriate tumor-specific mutations;
- the use of a software program, including proprietary and open source components, which is hosted in the cloud and a part of our product candidate, to assist with the design of the patient-specific mRNA, which software must be maintained and secured;
- effective design of the patient-specific mRNA that encodes for the required neoantigens;
- batch-specific manufacturing failures or issues that arise due to the uniqueness of each patient-specific batch that may not have been foreseen;
- quality control testing failures;
- unexpected failures of batches placed on stability;
- shortages or quality control issues with single-use assemblies, consumables or critical parts sourced from third-party vendors that must be changed out for each patient-specific batch;
- significant costs associated with individualized manufacturing that may adversely affect our ability to continue development;
- successful and timely manufacture and release of the patient-specific batch;
- shipment issues encountered during transport of the batch to the site of patient care;
- the ability to define a consistent safety profile at a given dose when each participant receives a unique treatment; and
- our reliance on single source suppliers.

We also continue to evolve our own custom manufacturing equipment. This equipment may not function as designed, which may lead to deviations in the drug product being produced. This can lead to increased batch failure and the inability to supply patients enrolled in the clinical trial. If our clinical development plans are expanded, we may not be able to supply this expanded need reliably without significant investments due to the custom nature of the equipment and single-use assemblies. In addition, there will be considerable time to scale up our facilities or build new facilities before we can begin to meet any commercial demand if one or more of our individualized product candidates are approved. This expansion or addition of new facilities could also lead to product comparability issues, which can further delay introduction of new capacity.

For those of our product candidates that are manufactured for each individual patient, we are required to maintain a chain of identity with respect to each patient's tissue sample, the sequenced data derived from such tissue sample, the results of such patient's genomic analysis and the custom manufactured product for such patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in product mix-up, adverse patient outcomes, loss of product, or regulatory action, including withdrawal of any approved products from the market. Further, as our product candidates are developed through early-stage clinical studies to later-stage clinical trials towards approval and commercialization, we expect that multiple aspects of the complicated collection, analysis, manufacture and delivery processes will be modified in an effort to optimize processes and results. These changes may not achieve the intended objectives, and any of these changes could cause our product candidates to perform differently than we expect, potentially affecting the results of clinical trials.

Our inability to manufacture sufficient or appropriate quantities of our COVID-19 vaccine or any of our product candidates, or our failure to comply with applicable regulatory requirements, could materially and adversely affect our business.

Manufacturing is a vital component of our individualized immunotherapy approach, and we have invested significantly in our manufacturing facilities, including the acquisition of a manufacturing site in Marburg, Germany, the construction of a novel modular manufacturing facility that we refer to as a "BioNTainer," and the construction of a facility to support manufacturing of our Individualized Vaccines Against Cancer (IVAC) candidates. All internal manufacturing is performed under GMP guidelines. We also rely on a network of CMOs for the manufacture of our COVID-19 vaccine. We do not rely on any external CMOs for the manufacture of our individualized product candidates and at this time, and we have limited redundancy among our facilities. Due to the individualized nature of our product candidates, we do not maintain product reserves. If any of our or our external CMOs' manufacturing facilities, including our BioNTainer units, experience difficulties, including related to manufacturing, product release, shelf life, testing, storage and supply chain management or shipping, our clinical development programs may be delayed or suspended until we or our external CMOs can resume operations. We may also be required to incur significant expenditures to resolve such difficulties.

We and our collaboration partner also have experienced, and continue to face the risk of, inventory write-downs or redundant production capacities with respect to our COVID-19 vaccine. Planned new formulations of our COVID-19 vaccine, including versions that could protect against new variants of COVID-19, have resulted or may result in significant research and development expense that was not or may not be recouped. In addition, we have experienced in the past, and may experience in the future, redundant production capacities under our agreements with CMOs due to planned new formulations, adaptations of our COVID-19 vaccine and increased internal manufacturing capacities. Significant inventory write-downs or redundant manufacturing expenses would negatively impact our results of operations.

Our facilities are subject to various regulatory requirements and may be subject to announced or unannounced inspections by the FDA or other regulatory authorities at any time during the development or commercialization phase. If we or our external CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, the EMA or comparable regulatory authorities in other jurisdictions, we may not be able to rely on our or our external CMOs' manufacturing facilities for the manufacture of our product candidates. If the FDA, the EMA or another comparable regulatory authority finds our or our external CMOs' facilities inadequate for the manufacture of our COVID-19 vaccine or our product candidates or otherwise deficient, including as a result of a site inspection, such facilities may be the subject of adverse regulatory action, including the issuance of untitled or warning letters. If such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly delay or otherwise impact our ability to develop, obtain regulatory approval for or market our COVID-19 vaccine or our product candidates.

Additionally, we may experience manufacturing difficulties due to resource constraints, labor disputes or unstable political environments. If we were to encounter any of these difficulties, our ability to provide our product candidates to patients in clinical trials, or to provide approved products for the treatment of patients, would be jeopardized.

We are subject to regulatory and operational risks associated with the physical and digital infrastructure at both our internal manufacturing facilities and at those of our external service providers.

The designs of our facilities are based on current standards for biotechnology facilities. They have been reviewed and approved by local authorities and have also received GMP manufacturing licenses. We have designed our facilities to incorporate a significant level of automation of equipment with integration of several digital systems to improve efficiency of operations. We have attempted to achieve a high level of digitization for clinical and commercial manufacturing facilities relative to industry standards. While this is meant to improve operational efficiency, this may pose additional risk of

process equipment malfunction and even overall manufacturing system failure or shutdown due to internal or external factors including, but not limited to, design issues, system compatibility or potential cybersecurity breaches. This may lead to a delay in supply or shutdown of our facilities. Any disruption in our manufacturing capabilities could cause delays in our production capacity for our drug substances or drug products, impose additional costs, or require us to identify, qualify and establish an alternative manufacturing site, the occurrence of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

As we expand our development and commercial capacity, we may continue to establish additional manufacturing capabilities in different jurisdictions, which may lead to regulatory delays or prove costly. If we fail to select the correct location, complete the construction in an efficient manner, recruit required personnel, and/or generally manage our growth effectively, the development and production of our products or product candidates could be delayed or curtailed. Additional investments may be needed if changes in our manufacturing process lead to required changes in our infrastructure.

Our COVID-19 vaccine and certain of our product candidates rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

Our product candidates require many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product, and suppliers may not be able to deliver raw materials to our specifications. In addition, some such suppliers normally support blood-based hospital businesses and generally do not have the capacity to support commercial products manufactured under GMP by biopharmaceutical firms. These suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also do not have contracts with many of these suppliers, and we may not be able to contract with them on acceptable terms or at all. Accordingly, we have experienced and we may in the future experience delays in receiving key raw materials to support clinical or commercial manufacturing.

In addition, some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Further, we may be unable to enter into agreements with a new supplier on commercially reasonable terms or at all, which could have a material adverse impact on our business.

We are subject to significant regulatory oversight with respect to manufacturing our products and product candidates. Our manufacturing facilities or the manufacturing facilities of our third-party manufacturers or suppliers may not meet regulatory requirements. Failure to meet GMP requirements set forth in regulations promulgated by the FDA, the EMA and other comparable regulatory authorities could result in significant delays in and costs of our products.

The manufacturing of immunotherapies for clinical trials or commercial sale is subject to extensive regulation. GMP requirements govern manufacturing processes and procedures, including record-keeping, and the implementation and operation of quality systems to control and assure the quality of products and materials used in our products and product candidates. Poor control of the GMP production processes can lead to product quality failures that can impact our ability to supply product, resulting in loss of potential product sales revenue, cost overruns and delays to clinical timelines for our clinical programs, which could be extensive. Such production process issues include but are not limited to:

- critical deviations in the manufacturing process;
- facility and equipment failures;
- contamination of the product due to an ineffective quality control strategy;
- facility contamination as assessed by the facility and utility environmental monitoring program;
- ineffective process, equipment or analytical change management, resulting in failed lot release criteria;
- raw material failures due to ineffective supplier qualification or regulatory compliance issues at critical suppliers;
- ineffective product stability;

- failed lot release or facility and utility quality control testing;
- ineffective corrective actions or preventative actions taken to correct or avoid critical deviations due to our developing understanding of the manufacturing process as we scale; and
- failed or defective components or consumables.

We must supply all necessary documentation in support of a BLA or other marketing authorization application on a timely basis and must adhere to the FDA's, the EMA's and other countries' GMP requirements, which are enforced, in the case of the FDA, in part through its facilities inspection program.

Regulatory authorities typically require representative manufacturing site inspections to assess adequate compliance with GMPs and manufacturing controls as described in the filing. If either we or one of our third-party manufacturing sites fail to provide sufficient quality assurance or control, approval to continue delivery of our commercial product or to commercialize our product candidates may not be granted. Inspections by regulatory authorities may be announced or unannounced and may occur at any time during the development or commercialization phase. The inspections may be product-specific or facility-specific for broader GMP inspections, or as a follow up to market or development issues that the regulatory agency may identify. Deficient inspection outcomes may result in adverse regulatory action, including the issuance of untitled or warning letters, which could influence our ability, or the ability of our third-party manufacturers or suppliers, to fulfill supply obligations, impacting or delaying supply or delaying programs. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including, but not limited to, clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates (including those of our collaborators) and our overall business operations.

The manufacturing process for any product is subject to the FDA's, the EMA's and other regulatory authorities' approval processes, and we may need to contract with manufacturers whom we believe can meet applicable regulatory authority requirements on an ongoing basis. If we or our third-party manufacturers are unable to reliably manufacture to specifications acceptable to the FDA, the EMA or other regulatory authorities, we or our collaborators may not obtain or maintain the approvals we or they need to release and deliver such products. Even if we or our collaborators obtain regulatory approval for any of our immunotherapies, there is no assurance that either we or our CMOs will be able to manufacture our product candidates to specifications acceptable to the FDA, the EMA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts or increase our cost of goods. The occurrence of any of the foregoing could have an adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, we may not have direct control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our CMOs are engaged with other companies to supply or manufacture materials or products for such companies, which exposes our CMOs to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may generally affect the regulatory status of our CMOs' facilities, and could result in the sanctions and other adverse outcomes described above. Our potential future dependence upon others for the manufacture of our products, product candidates and raw materials may adversely affect our future operating results and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

The FDA, the EMA and other regulatory authorities may require us to submit product samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA or other regulatory authorities may require that we do not distribute a lot or lots until the relevant agency authorizes such release. Deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Our CMOs have, in the past, experienced lot failures and some may have experienced product recalls. Lot failures or product recalls with respect to product produced by either our own facilities or those of our third-party manufacturers could cause us and our collaborators to delay clinical trials, product launches or product supply, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

We also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate our manufacturing processes and operations, which could result in delays in production or

difficulties in maintaining compliance with applicable regulatory requirements. While we train and qualify all personnel around the appropriate handling of our products and materials, we may not be able to control for or ultimately detect intentional sabotage or negligence by any employee or contractor.

Risks Related to our Reliance on Third Parties

We rely on third parties in the conduct of significant aspects of our preclinical studies and clinical trials and intend to rely on third parties in the conduct of future clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements or fail to meet expected deadlines, we may be unable to obtain regulatory approval for our product candidates.

We currently rely, and expect to continue to rely, on third parties, such as CROs, clinical data management organizations, collaborators, medical institutions and clinical investigators, to conduct various and significant elements of our clinical trials. Furthermore, we currently rely, and expect to continue to rely, on third parties to conduct certain research and preclinical testing activities. In some cases, these third parties may terminate their engagements with us. If we need to enter into alternative arrangements, it would delay our discovery or product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory or contractual responsibilities. We are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. For example, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial.

Moreover, the FDA requires us to comply with GCP for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a U.S. government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and our CROs are required to comply with regulations, including GCP, for conducting, monitoring, recording and reporting the results of preclinical studies and clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial participants are adequately informed, among other things, of the potential risks of participating in clinical trials. We are also responsible for ensuring that the rights of our clinical trial participants are protected. These regulations are enforced by the FDA, the regulatory authorities of the EU member states, and comparable regulatory authorities of other jurisdictions for any product candidates in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable regulatory authorities of other jurisdictions may require us to perform additional clinical trials before approving our marketing applications. We cannot be sure that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCP. In addition, our clinical trials must be conducted with product candidates produced in accordance with the requirements of GMP regulations. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action.

Although we have designed, and in the future intend to design the clinical trials for certain of our product candidates, our collaborators will design the clinical trials that they are managing (in some cases, with our input) and in the case of clinical trials controlled by us, we expect that CROs will conduct all of the clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, are outside of our direct control. Our reliance on third parties to conduct future preclinical studies and clinical trials results in less direct control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also potentially lead to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;

- undergo changes in priorities or become financially distressed;
- form relationships with other entities, some of which may be our competitors;
- make human errors; or
- be subject to cyberattacks.

These factors may materially adversely affect the willingness or ability of third parties to conduct our preclinical studies and clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs do not perform preclinical studies and clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates, or our development programs may be materially and irreversibly harmed. If we are unable to rely on preclinical and clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

We also rely on other third parties to transport, store and distribute the required materials for our clinical trials. In the past, certain of our third-party vendors have mishandled our materials, resulting in loss of full or partial lots of material. Any further performance failure on the part of these third parties could result in damaged products and could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, if approved, producing additional losses and depriving us of potential product sales revenue, causing us to default on our contractual commitments, result in losses that are not covered by insurance, and damage our reputation and overall perception of our products in the marketplace. Each of the risks set forth above continues to be affected by the spread of COVID-19 globally, even as the virus begins to enter an endemic phase.

Our existing collaborations, or any future collaboration arrangements that we may enter into, may not be successful, which could significantly limit the likelihood of receiving the potential economic benefits of the collaboration and adversely affect our ability to develop and commercialize our products and product candidates.

We have entered into collaborations under which our collaborators have provided, and may in the future provide, funding and other resources for developing and commercializing our products and product candidates. We expect to enter into additional collaborations to access additional funding, capabilities and/or expertise in the future. Our existing collaborations, and any future collaborations we enter into, may pose a number of risks, including the following:

- collaborators may not perform or prioritize their obligations as expected;
- the clinical trials conducted as part of such collaborations may not be successful;
- collaborators may not pursue development and commercialization of any product candidates and products that achieve regulatory approval or may elect not to continue or renew development or commercialization of programs based on clinical trial results, changes in the collaborators' focus or available funding (for example, we are aware that there have been allegations that Fosun International Ltd., an affiliate of our collaboration partner Fosun Pharma, is facing liquidity risks), or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates developed in collaborations with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development or commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, may lead to additional responsibilities for us with

respect to such product candidates, or may result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly maintain, protect, defend or enforce our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborations may be terminated for the convenience of the collaborator and, if terminated, the development of our product candidates may be delayed, and we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates;
- future relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business;
- we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex; and
- our international operations through any future collaborations, acquisitions or joint ventures may expose us to certain operating, legal and other risks not encountered in Germany or the United States.

If our collaborations do not result in the successful development and commercialization of programs, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone, earn-out, royalty or other contingent payments, or otherwise yield the expected benefits under the collaborations. As a result, our development of product candidates and commercialization efforts could be delayed and we may need additional resources to develop and commercialize our product candidates. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization described in this report apply to the activities of our collaborators.

If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our research, development and commercialization plans.

Our research and product development programs and the potential commercialization of any product candidates we develop alone or with collaborators will require substantial additional cash to fund expenses, and we expect that we will continue to seek collaborative arrangements with others in connection with the development and potential commercialization of current and future product candidates or the development of ancillary technologies. We face significant competition in establishing relationships with appropriate collaborators. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Whether or not we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include, among other things and as applicable for the type of potential product or technology, an assessment of the opportunities and risks of our technology, the design or results of studies or trials, the likelihood of approval, if necessary, of the FDA or comparable regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and technologies and industry and market conditions generally.

Current or future collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us. Additionally, we may be restricted under existing collaboration agreements from entering into future agreements on certain terms or for certain development activities with potential collaborators. For example, we have granted exclusive rights or options to Pfizer for certain targets, and under the terms of our respective collaboration agreements with them, we will be restricted from granting rights to other parties to use our mRNA technology to pursue potential products that address those targets. Similarly, our collaboration agreements have in the past and may in the future contain non-competition provisions that could limit our ability to enter into collaborations with future collaborators.

Collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we do enter into additional collaboration agreements, the negotiated terms may force us to relinquish rights that diminish our potential profitability from development and commercialization of the subject product candidates or others. If we are unable to enter into additional collaboration agreements, we may have to curtail the research and development of the product candidate or technology for which we are seeking to collaborate, reduce or delay research and development programs, delay potential commercialization timelines, reduce the scope of any sales or marketing activities or undertake research, development or commercialization activities at our own expense. If we elect to increase our expenditures to fund research, development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all.

We have entered into in-licensing arrangements and may form or seek to enter into additional licensing arrangements in the future, and we may not realize the benefits of such licensing arrangements.

We are a party to licenses that give us rights to third-party intellectual property, including patents and patent applications, that are necessary or useful for our business. In particular, we have obtained licenses from Acuitas Therapeutics, CellScript LLC and its affiliate, mRNA RiboTherapeutics, Inc., to patent rights claiming certain uses of modified RNA, as well as licenses from certain other parties for intellectual property useful in pharmaceutical formulations. We may enter into additional licenses to third-party intellectual property in the future.

The success of products developed based on in-licensed technology will depend in part on the ability of our current and future licensors to prosecute, obtain, maintain, protect, enforce and defend patent protection for our in-licensed intellectual property. Our current and future licensors may not successfully prosecute the patent applications we license. Even if patents were issued in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. In addition, we sublicense our rights under various third-party licenses to our collaborators. Any impairment of these sublicensed rights could result in reduced revenues under our collaboration agreements or result in termination of an agreement by one or more of our collaborators.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate the intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other intellectual property rights to third parties under collaborative relationships;
- our diligence obligations with respect to the use of the licensed intellectual property and technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions, trade secrets, know-how and other intellectual property resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology; and
- including amounts to be paid pursuant to certain program milestones being achieved or to royalty obligations, including the triggering of royalty obligations and amounts to be paid pursuant thereto.

If disputes over intellectual property that we have in-licensed or other related contractual rights prevent or impair our ability to maintain our current licensing arrangements on favorable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we, our co-owners or our licensors fail to adequately protect, defend, maintain or enforce this intellectual property, our ability to commercialize products could suffer.

We and our collaborators rely on third parties to manufacture certain of our clinical product supplies, and we may have to rely on third parties to produce and process our product candidates, if approved.

Although we expect to continue using our own clinical manufacturing facilities where available, we also rely on outside vendors to manufacture supplies and process our product candidates. We only manufacture our COVID-19 vaccine on a commercial scale and may not be able to achieve commercial-scale manufacturing and processing for our other product candidates, if approved, and may be unable to create an inventory of mass-produced, off-the-shelf product to satisfy demands for our product candidates, if approved.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing and processing of our product candidates, and the actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may not be able to develop commercially viable products other than our COVID-19 vaccine.

In addition, our reliance on a limited number of CMOs exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA or other regulatory authorities may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of regulatory authority questions, if any;
- our CMOs might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- CMOs may not be able to execute our manufacturing procedures appropriately;
- our future CMOs may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the U.S. Drug Enforcement Administration and corresponding state agencies and by regulatory authorities in other jurisdictions to ensure strict compliance with GMP and other government regulations and corresponding standards in other jurisdictions. We do not have control over CMOs' compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made in the manufacturing process for our products;
- our CMOs could breach or terminate their agreement with us; and
- our CMOs would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above.

Each of these risks could delay our clinical trials, the approval, if any, of our COVID-19 vaccine or product candidates by the FDA or regulatory authorities in other jurisdictions or the commercialization of our COVID-19 vaccine or product candidates, or result in higher costs or deprive us of potential product sales revenue. In addition, we will rely on third parties to perform release tests on our COVID-19 or our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

Certain of our collaborators currently rely on CMOs located outside of the United States to manufacture their clinical materials, and we expect to rely on CMOs located outside of the United States in the future. Such ex-U.S. CMOs may be subject to or affected by U.S. legislation, executive orders, regulations, or investigations, including but not limited to the proposed BIOSECURE Act, the Executive Order on Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern, sanctions, trade restrictions and other U.S. and other regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material, delay or impact clinical trials, have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies and adversely affect our financial condition and business prospects.

We are dependent on single source suppliers for some of the components and materials used in, and the processes required to develop, our COVID-19 vaccine and our product candidates.

We currently depend on single source suppliers for some of the components and materials used in, and manufacturing processes required to develop, our COVID-19 vaccine and our product candidates. We cannot ensure that these suppliers or

service providers will remain in business, or have sufficient capacity or supply to meet our needs, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single source suppliers of raw materials, components, key processes and finished goods exposes us to several risks, including disruptions in supply, price increases or late deliveries. There are, in general, relatively few alternative sources of supply for substitute components. These vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single source supplier or service provider could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects.

If we have to switch to a replacement supplier, the manufacture and delivery of our product candidates could be interrupted for an extended period, which could adversely affect our business. Establishing additional or replacement suppliers for any of the components or processes used in our COVID-19 vaccine and our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single source components and materials used in our COVID-19 vaccine and our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our COVID-19 vaccine and product candidates.

In addition, as part of the FDA's approval of our product candidates, we will also require FDA review of the individual components of our process, which include the manufacturing processes and facilities of our single source suppliers.

Our reliance on these suppliers, service providers and manufacturers subjects us to a number of risks that could harm our reputation, business and financial condition, including, among other things:

- delays to the development timelines for our product candidates;
- interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;
- difficulty and cost associated with locating and qualifying alternative suppliers for our components in a timely manner;
- production delays related to the evaluation and testing of components from alternative suppliers, and corresponding regulatory qualifications;
- delay in delivery due to our suppliers' prioritizing other customer orders over ours;
- damage to our reputation caused by defective components produced by our suppliers; and
- fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

If any of these risks materialize, costs could significantly increase and our ability to meet demand for our products could be impacted.

Risks Related to our Intellectual Property

If our efforts to obtain, maintain, protect, defend and/or enforce the intellectual property related to our COVID-19 vaccine or our product candidates and technologies are not adequate, we may not be able to compete effectively in our market.

Our commercial success depends in part on our ability to obtain, maintain, protect, defend and enforce patent and other intellectual property, including trade secret and know-how, protection for our COVID-19 vaccine and for our product candidates, proprietary technologies and their uses, as well as our ability to operate, develop, manufacture and commercialize our COVID-19 vaccine or one or more of our product candidates without infringing, misappropriating or otherwise violating the intellectual property or other proprietary rights of our competitors or any other third parties,

including any non-practicing entities or patent assertion entities. We generally seek to protect our intellectual property position by filing and/or licensing patent applications in the European Union, the United States and elsewhere related to our product candidates, proprietary technologies (including methods of manufacture) and their uses that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent that the issued claims cover third parties' activities in the countries in which they are performed. We cannot be certain that the claims in any of our patent applications will be considered patentable by the United States Patent and Trademark Office, or the USPTO, courts in the United States or the patent offices and courts in other jurisdictions, including Europe, nor can we be certain that any claim in our issued patents will not be found invalid or unenforceable if challenged. Accordingly, there can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will adequately cover our COVID-19 vaccine or our product candidates, or otherwise afford sufficient protection against competitors with similar technology, nor can there be any assurance that issued patents will not be infringed, designed around, invalidated or held unenforceable. Furthermore, we may not be able to apply for patents on certain aspects of our current or future products or product candidates, proprietary technologies and their uses in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent protection we obtain may not be sufficient to prevent substantial competition.

Even claims of issued patents may later be found invalid or unenforceable, or may be modified or revoked in proceedings before various patent offices or in courts in the United States, Europe or other jurisdictions. The degree of future protection for our intellectual property and other proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we do not adequately obtain, maintain, protect, defend and enforce our intellectual property and proprietary technology, competitors may be able to use our products, product candidates and proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our current or future licensors or collaborators will be successful in prosecuting, obtaining, protecting, maintaining, enforcing or defending patents and patent applications necessary or useful to protect our products or product candidates, proprietary technologies (including methods of manufacture) and their uses. These risks and uncertainties include, from time to time, the following:

- the USPTO and various other governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patenting process, the noncompliance with which can result in abandonment or lapse of a patent or patent application or a finding that a patent is unenforceable, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- claims of issued patents that we own (solely or jointly) or have in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- other parties may have designed around our patent claims or developed technologies that may be related or competitive to our COVID-19 vaccine or to our product candidates or other technologies, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent filings, either by claiming the same or overlapping methods, products, reagents, tools or devices or by claiming subject matter that could dominate one or more of our patent claims;
- any successful opposition to claims of any patents owned by or in-licensed to us could deprive us of rights necessary for the development and exploitation of our COVID-19 vaccine or our product candidates and other technologies, or the successful commercialization of any product candidates and other technologies that we may develop;
- because patent applications in the United States and most other jurisdictions are confidential for a period of time after filing, we cannot be certain that we, our co-owners or our licensors were the first to file any patent application related to our product candidates, proprietary technologies and their uses;
- a court or patent office proceeding, such as a derivative action or interference, can be provoked or instituted by a third party or a patent office, and might determine that one or more of the inventions described in our patent filings, or in those we licensed, was first invented by someone else, so that we may lose rights to such invention(s);

- a court or other patent proceeding, such as an inter partes review, post grant review or opposition, can be instituted by a third party to challenge the inventorship, scope, validity and/or enforceability of our patent claims and might result in invalidation or revision of one or more of our patent claims, or in a determination that such claims are unenforceable;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; existing legislation (for example, in the United States, the Public Readiness and Emergency Preparedness Act, etc.) may be interpreted, and new legislation may be passed, to permit third-party use of patented technologies relating to a public health concern, with little or no compensation to the patent holder(s); and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing competitors a better opportunity to create, develop and market competing product candidates.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. The standards that the USPTO and its counterparts use to grant patents are not always applied predictably or uniformly and can change. Similarly, the ultimate degree of protection that will be afforded to biotechnology inventions, including ours, in the United States and other countries, remains uncertain and is dependent upon the scope of the protection decided upon by patent offices, courts and lawmakers. Moreover, there are periodic changes in patent law, as well as discussions in the U.S. Congress and in other jurisdictions about modifying various aspects of patent law. There is no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. In certain countries, for example, methods for the medical treatment of humans are not patentable. More generally, the laws of some countries do not protect intellectual property rights to the same extent as U.S. or EU laws, and those countries may lack adequate rules and procedures for granting, maintaining, protecting, defending and enforcing our intellectual property rights.

Furthermore, the patent prosecution process is expensive and time-consuming, and we may not be able to file, prosecute, maintain, protect, defend, enforce or license all necessary or desirable patents or patent applications, as applicable, at a reasonable cost or in a timely manner. It is possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties, if any of these parties were to breach such agreements and improperly disclose such output before a patent application is filed, this could jeopardize our ability to seek patent protection. We also rely to a certain extent on trade secrets, know-how, and technology, which are not protected by patents, to maintain our competitive position. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

The issuance of a patent is not conclusive as to its inventorship, priority date, scope, term, validity or enforceability so that any patents that may issue or that we may license may be challenged in the courts or patent offices in the United States, Europe and other jurisdictions. Once granted, patents may remain open to a variety of challenges, including opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings, and furthermore, may be challenged as a defense in any enforcement action that we might bring; for example, various third parties have filed opposition papers challenging our issued EP patent number 2714071, which relates to our iNeST product candidates, and whose claims recite steps relating to neoantigen selection. While the claims of our issued EP patent 2714071 were upheld after opposition, there is currently a pending appeal against the opposition decision. Such challenges may result in loss of exclusivity or in patent claims being narrowed, terminated, disclaimed, invalidated, assigned to others or held unenforceable, any or all of which could limit our ability to stop others from using or commercializing similar or identical products, or limit the scope and/or term of patent protection of our products and product candidates and/ or eliminate it altogether, thus hindering or removing our ability to limit third parties from making, using or selling products or technologies that are similar or identical to ours, and/or reduce or eliminate royalty payments to us from our licensees. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, our pending and future patent applications may not result in patents being issued which protect our technology or our product(s) or product candidates, or which effectively prevent others from commercializing competitive technologies and products. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our ability to enforce our owned and in-licensed patent and other intellectual property rights depends on our ability to detect infringement, misappropriation and other violation of such patents and other intellectual property. It may be difficult to detect infringers, misappropriators and other violators who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement, misappropriation or other violation in a competitor's or potential competitor's product or service, and in some cases we may not be able to introduce obtained evidence into a proceeding or otherwise utilize it to successfully demonstrate infringement. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

Furthermore, patents or other intellectual property rights that we may be able to secure for our COVID-19 vaccine or our other COVID-19 vaccine candidates could be restricted or preempted if governments determine that they will not enforce, or will require compulsory licensing of, technologies useful to address the spread of COVID-19.

In addition, proceedings to enforce or defend our owned or in-licensed patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. If any of our owned or in-licensed patents covering our product candidates or other technologies are narrowed, invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our product candidates or other technologies, our competitive position could be harmed or we could be required to incur significant expenses to protect, enforce or defend our rights. If we initiate lawsuits to protect, defend or enforce our patents, or litigate against third-party claims, such proceedings would be expensive and would divert the attention of our management, technical personnel, and other employees even if the eventual outcome is favorable to us.

The degree of future protection for our intellectual property and other proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product(s), our product candidates and other technologies;
- any of our pending patent applications or those of our licensors may issue as patents;
- others will not or may not be able to make, use, offer to sell or sell products that are the same as or similar to our own but that are not covered by the claims of the patents that we own or license;
- we will be able to successfully commercialize our products on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we were the first to make the inventions covered by each of the patents and pending patent applications that we own or license;
- we, our co-owners or our licensors were the first to file patent applications for these inventions;
- others will not develop similar or alternative products or technologies that do not infringe the patents we own or license;
- any of the claims of patents we own or license will be found to ultimately be valid and enforceable;
- any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates and other technologies or will provide us with any competitive advantages;
- a third party may not challenge the claims of patents we own or license and, if challenged, a court would hold that such patent claims are valid, enforceable and infringed;
- we may develop or in-license additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our ability to issue patents, or otherwise on our business;
- our competitors do not conduct research, development, testing or commercialization activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we will develop additional proprietary technologies, product(s) or product candidates that are separately patentable; and

- our, or our collaborators', development and commercialization activities, including our manufacturing processes, or products will not infringe patents of our competitors or any other third parties, including any non-practicing entities or patent assertion entities.

Other companies or organizations may challenge our intellectual property rights or the intellectual property rights of our partners or may assert intellectual property rights that prevent us or our partners from developing and commercializing our COVID-19 vaccine or our product candidates and other technologies.

We practice in new and evolving scientific fields, the continued development and potential use of which has resulted in many different patents and patent applications from organizations and individuals seeking to obtain intellectual property protection in the fields. We own and in-license patent applications and issued patents that describe and/or claim certain technologies, including products, reagents, formulations, tools and methods including uses and manufacturing methods, or features or aspects of any of these. These issued patents and pending patent applications claim certain compositions of matter and methods relating to the discovery, development, testing, manufacture and commercialization of therapeutic modalities and our delivery technologies, including lipid nanoparticles, or LNPs. If we, our co-owners or our licensors are unable to obtain, maintain, protect, defend or enforce patent protection with respect to our products, product candidates and other technology and any other products, product candidates and technology that we may develop, our business, financial condition, results of operations and prospects could be materially harmed.

As the scientific fields mature, our known competitors and other third parties, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents, and they have filed and will continue to file patent applications claiming inventions in the fields in the United States and elsewhere. This may limit, interfere with or eliminate our and our partners' ability to make, use, sell, import or otherwise exploit our COVID-19 vaccine or our product candidates or other technologies. There is uncertainty about which patents will issue, and, if they do, as to when, to whom and with what claims. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors.

We, our co-owners, our partners or our licensors may in the future become a party to patent proceedings or priority disputes in the United States, Europe or other jurisdictions. In the United States, the Leahy-Smith America Invents Act, or the America Invents Act, includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent through USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. We expect that our competitors and other third parties will institute litigation and other proceedings, such as interference, reexamination and opposition proceedings, as well as inter partes and post-grant review proceedings against us and the patents and patent applications that we own and in-license. For example, various third parties have filed oppositions challenging our issued EP patent 2714071 which relates to our iNeST product candidates, and whose claims recite steps relating to neoantigen selection. While the patent was upheld through the opposition proceedings, some of the opposing parties have appealed that decision.

Additionally, we face ongoing COVID-19 vaccine-related patent litigation. Alnylam Pharmaceuticals Inc. has brought litigation against us and Pfizer regarding U.S. Patent Nos. 11,245,933; 11,382,979; 11,633,479; 11,633,480; 11,612,657; and 11,590,229, the latter five of which are continuations of the '933 Patent. In addition, CureVac SE initiated litigation against us regarding European patents 1857122B1 and 3708668B1 (EP'122 and EP'668 Patents), and three German utility models, or the CureVac IP, in Germany, and then a subsequent litigation was brought by us and Pfizer in the United States regarding U.S. Patent Nos. 11,135,312, 11,149,278 and 11,241,493 that are "U.S. counterparts" to the CureVac IP. CureVac responded with counterclaims asserting infringement of seven additional U.S. patents, U.S. Patent Nos. 10,760,070; 11,286,492; 11,345,920; 11,471,525; 11,576,966; 11,596,686, and 11,667,910. BioNTech and Pfizer also initiated proceedings seeking the revocation of the EP'122 and EP'668 Patents in the Business and Property Courts of England and Wales. In addition, BioNTech filed a nullity action in the Federal Patent Court of Germany seeking a declaration that the EP'122 Patent is invalid, initiated cancellation actions against the CureVac IP in the German Patent and Trademark Office, and filed an opposition proceeding in the European Patent Office seeking the revocation of EP'668. CureVac initiated a second litigation against us in Germany regarding European patent EP4023755B1 (EP'755 Patent), and two Utility Models DE202021004123U1 and DE202021004130U1. BioNTech filed an opposition proceeding seeing the revocation of EP'755 and cancellation actions against DE'123 and DE'130. ModernaTX, Inc., or Moderna, has brought litigation against us and Pfizer regarding European patents 3590949B1 and 3718565B1 (EP'949 and EP'565 Patents) in Germany, England and Wales, the Netherlands, Ireland, and Belgium, and regarding U.S. Patent Nos. 10,898,574,

10,702,600, and 10,933,127 in the United States. BioNTech and Pfizer also initiated proceedings seeking the revocation of the EP'949 and EP'565 Patents in the Business and Property Courts of England and Wales and have filed opposition proceedings in the European Patent Office seeking the revocation of the EP'949 and EP'565 Patents. BioNTech and Pfizer have filed petitions for *inter partes* review before the Patent Trial and Appeal Board in the U.S. with respect to U.S. Patent Nos. 10,702,600 and 10,933,127. Arbutus Biopharma Corp. and Genevant Sciences GmbH have brought litigation against us and Pfizer in the United States regarding U.S. Patent Nos. 9,504,651; 8,492,359; 11,141,378; 11,298,320; and 11,318,098. Promosome initiated litigation against us and Pfizer in the United States regarding U.S. Patent No. 8,853,179; it has since been dismissed with prejudice. We cannot guarantee that we will not become subject to additional COVID-19 vaccine patent infringement lawsuits in the future. In addition, should Pfizer not prevail in any of the ongoing COVID-19 vaccine patent infringement lawsuits to which it is a party, Pfizer may seek to require us to indemnify Pfizer for losses suffered therefrom as well as any losses from future COVID-19 vaccine patent infringement lawsuits in which it does not prevail. We believe we have strong defenses against each of these claims and intend to vigorously defend ourselves in each proceeding, but we can make no assurances regarding the ultimate outcome of any of these matters.

We expect that we will continue to be subject to similar proceedings or priority disputes, including oppositions, in Europe or other jurisdictions relating to patents and patent applications in our portfolio.

If we, our co-owners, our partners or our licensors are unsuccessful in any interference proceedings or other priority or validity disputes, including any derivations, post-grant review, *inter partes* review or oppositions, to which we or they are subject, we may lose valuable intellectual property rights through the narrowing or loss of one or more patents owned or in-licensed, or our owned or in-licensed patent claims may be narrowed, invalidated or held unenforceable. In many cases, the possibility of appeal exists for either us or our opponents, and it may be years before final, unappealable rulings are made with respect to these patents in certain jurisdictions. The timing and outcome of these and other proceedings is uncertain and may adversely affect our business if we are not successful in defending the patentability and scope of our pending and issued patent claims. Even if our rights are not directly challenged, disputes could lead to the weakening of our intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management, technical personnel and other employees and could have a material adverse impact on our business and our ability to successfully compete against our current and future competitors.

There are many issued and pending patent filings that claim aspects of technologies that we may need for our mRNA products or product candidates, or other product candidates, including patent filings that relate to relevant delivery technologies. There are also many issued patents that claim targeting genes or portions of genes that may be relevant for immunotherapies we wish to develop. In addition, as evidenced by the lawsuits brought against Moderna, Pfizer and us, there may be additional issued and pending patent applications that may be asserted against us in a court proceeding or otherwise based upon the asserting party's belief that we may need such patents for the development, manufacturing, testing and commercialization of our COVID-19 vaccine or of our product candidates. Thus, it is possible that one or more organizations, ranging from our competitors to non-practicing entities or patent assertion entities, has or will hold patent rights to which we may need a license, or hold patent rights which could be asserted against us. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If those organizations refuse to grant us a license to such patent rights on reasonable terms, if we fail to invalidate relevant patents, or if a court or other governing body determines that we need such patent rights that have been asserted against us and we are not able to obtain a license on reasonable terms or at all, we may be unable to perform research and development or other activities or market products covered by such patents, and we may need to cease the development, manufacture, testing and commercialization of one or more of the product candidates we may develop. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects.

We may not be successful in obtaining, maintaining, protecting or defending the necessary intellectual property rights to allow us to identify and develop product candidates, and test product components and manufacturing processes for our development pipeline.

We currently have rights to certain intellectual property through our owned and in-licensed patents and other intellectual property rights relating to identification, development and testing of our product candidates or other technologies. As our activities may involve additional product candidates or services that could require the use of intellectual property and other proprietary rights held by third parties, the growth of our business could depend in part on our ability to acquire, in-license or use such intellectual property and proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and these intellectual property and other proprietary rights may be held by others. We may be unable to secure such licenses or otherwise acquire or in-license any

compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary, on reasonable terms, or at all, for product candidates and other technologies that we may develop. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities.

We sometimes collaborate with academic institutions and/or utilize services of CROs and CMOs in certain aspects of our research or development under written agreements with these parties. These agreements may not ensure protection of intellectual property rights in developed technology, or may fail to provide us with sufficient control of or access to such intellectual property rights. For example, agreements with these academic institutions typically provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. However, these institutions may not honor our option and right of first negotiation for intellectual property rights or we may otherwise be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program or otherwise continue to develop certain product candidates or other technologies. CROs and/or CMOs may control certain technologies that were utilized in and/or developed through work on our behalf, and may not pursue protection of such technologies, or may provide us with only non-exclusive rights in such technologies, so that relevant technologies may be shared with other parties including our competitors. In any relationship with a third party, there is a risk of disagreement over intellectual property rights (including inventorship or ownership of, rights to protect and/or enforce, and/or rights to use) in utilized or developed technologies.

Moreover, some of our owned patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain, or continue to maintain, exclusive rights to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technologies. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In addition, third parties that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain, protect, defend or enforce the existing intellectual property rights we have, we may have to abandon the development and commercialization of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The lifespans of our patents may not be sufficient to effectively protect our products or product candidates, technologies and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date, assuming maintenance fees are timely paid after the patent has issued. Most other jurisdictions also provide a 20-year nominal patent term, though many require payment of regular, often annual, annuities to maintain pendency of an application or viability of an issued patent. In some jurisdictions, one or more options for extension of a patent term may be available, but even with such extensions, the lifespan of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, proprietary technologies and their uses are obtained, once the patent term has expired, we may be subject to competition from third parties that can then use the inventions included in such patents to create competing products and technologies. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. The USPTO can also require, in certain circumstances, that the expiration date of a subject patent be shortened by the filing of a terminal disclaimer over one or more patents that may expire sooner than the subject patent. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such candidates are commercialized. If any patents that we own or in-license expire, we would not be able to stop others from using or commercializing similar or identical technology and products, and our competitors could market competing products and technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process for a drug product subject to the provisions of the Hatch-Waxman Act. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. For example, we did not extend any patent for our COVID-19 vaccine. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are heavily reliant upon licenses to certain intellectual property and other proprietary rights from third parties that are important or necessary to the development and commercialization of our technology and product(s) or product candidates, and we expect to enter into similar license agreements in the future. Licensing of intellectual property is important to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Our licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop, test, or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in any or all of our licenses.

Where we obtain licenses from, or collaborate with, third parties, in some circumstances we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from, or that arises through collaboration with, such third parties, or such activities, if controlled by us, may require the input of such third parties. In some cases, patent prosecution (including preparation and filing) of our in-licensed intellectual property or of intellectual property developed through collaboration, is controlled solely by the licensor or collaborator. We may also require the agreement and/or cooperation of our licensors and collaborators to protect, enforce, utilize, or defend any in-licensed patent rights, and such agreement and/or cooperation may not be provided. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, protected, enforced or defended in a manner consistent with the best interests of our business. Any patents or patent applications that we in-license may be challenged, narrowed, circumvented, invalidated or held unenforceable, or our licensors may not properly maintain such patents or patent applications and they may expire. If our licensors fail to obtain, maintain, defend, protect or enforce the intellectual property we license from them, we could lose our rights to the intellectual property and our competitors could market competing products using the inventions in such intellectual property. In certain cases, we control the prosecution of patents included from in-licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our collaborators. If we and our licensors or collaborators disagree over IP protection strategies for relevant technologies, disputes may arise, and we could lose access to or control over protection of technologies important to our business. If so, we may not be able to adequately protect our product(s) or product candidates, including not being able to prevent a competitor or other third party from developing the same product(s) or product candidates for the same or a different use. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Moreover, we may disagree from time to time with licensors or collaborators regarding, among other things, the interpretation of each party's obligations or the amounts payable under our agreements. For example, we are in ongoing discussions with the University of Pennsylvania and the National Institute of Health, or NIH, concerning royalties and other related amounts allegedly owed on sales of our COVID-19 vaccine since commercialization. We and the NIH have exchanged detailed characterizations of our positions and NIH has delivered a communication threatening to send a notice

of default for breach of our agreement. While we disagree with the positions being taken by the University of Pennsylvania and NIH, the ultimate outcome of these matters is uncertain and we cannot guarantee that our interpretation of these license agreements will prevail, or that we will not ultimately need to pay some or all of the royalty and other related amounts in dispute.

If we are found to have failed to satisfy obligations or materially breached any of our agreements, such as licenses to third-party intellectual or any disagreements between us and our licensors, a licensor could potentially have the right or reason to terminate the license, to exercise the option of a non-exclusive license, which would allow our competitors to have access to the same intellectual property and technology licensed to us. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone and royalty payment, exclusivity and other obligations on us. If we fail to comply with our obligations under these agreements, including royalty payments, or we are subject to a bankruptcy, the licensor may have the right to terminate the license agreement, in which event we would not be able to develop, market and commercialize product(s) or product candidates covered by the license agreement. In spite of our best efforts and even if we disagree, our licensors might still conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop, test and commercialize the product(s) or product candidates covered by these license agreements. In the event that any of our license agreements were to be terminated by the licensor, we may need to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all. If these license agreements are rightfully terminated, or if the underlying patents or other intellectual property fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market and commercialize, products similar or identical to ours, and our licensors may be able to seek additional judicial remedies. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing license agreements in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Failure to prevail with respect to any contractual disagreements could result in a material adverse effect on our competitive position, business, financial conditions, results of operations or prospects, particularly if discussions result in legal or other dispute resolution proceedings.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described in this section. If we, our co-owners or our licensors fail to adequately protect this intellectual property, our ability to develop, test, market and commercialize our product(s) or product candidates could suffer. Moreover, if disputes over intellectual property that we have in-licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop, test, market and commercialize the affected product(s) or product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Some of our in-licensed intellectual property has been discovered through government-funded programs and thus may be subject to federal regulations such as “march-in” rights and certain reporting requirements, and compliance with such regulations may limit our exclusive rights and our ability to contract with manufacturers.

Certain intellectual property rights that have been in-licensed, including patent applications and patents that we in-license from the University of Pennsylvania, the Louisiana State University, the Broad Institute, the NIH, Genentech, and Cellscript, have been generated through the use of U.S. government funding and are therefore subject to certain federal regulations. The U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or the Bayh-Dole Act. These U.S. government rights may include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions covered by that Act for any governmental purpose. In addition, the U.S. government may have the right, under certain limited circumstances, to require the licensor to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if it determines that (i) adequate steps have not been taken to commercialize the invention, (ii) government action is necessary to meet public health or safety needs or (iii) government action is necessary to meet requirements for public use under federal regulations (also collectively referred to as “march-in rights”). The U.S. government may also have the right to take title to these inventions if the licensor fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects. Intellectual property generated under a government-funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources.

In addition, the U.S. government requires that any products embodying any such inventions or produced through the use of any such inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture the products substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. We may not be able to obtain a waiver of this preference for U.S. industry, and this preference may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our owned or in-licensed future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. If we or our licensors are unable to secure an exemption to these manufacturing requirements, if we comply with them, or if we are unable to comply with them, we may experience a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our current proprietary position for certain products and product candidates depends upon our owned or in-licensed patent filings covering components, manufacturing-related methods, formulations and/or methods of use, which may not adequately prevent a competitor or other third party from using the same product candidate for the same or a different use.

Composition of matter patent protection is generally considered to be desirable because it provides protection without regard to any particular method of use or manufacture or formulation. While we have pursued or obtained patent protection covering components of certain product candidates and tests, manufacturing-related methods, formulations and/or methods of use, we have not yet obtained patent protection for all components of certain product candidates and tests, manufacturing-related methods, formulations and/or methods of use. For instance, we do not currently have any claims in our owned or in-licensed issued U.S. patents that cover the overall construct used in our iNeST product candidates. We also cannot be certain that claims in any future patents issuing from our pending owned or in-licensed patent applications or our future owned or in-licensed patent applications will cover the composition of matter, tests, manufacturing-related methods, formulations and/or methods of use of our current or future product candidates. Method of use patents protect the use of a product for the specified method and formulation patents cover formulations to deliver therapeutics. These types of patents do not prevent a competitor or other third party from developing, testing, marketing or commercializing a similar or identical product for an indication that is outside the scope of the patented method or from developing a different formulation that is outside the scope of the patented formulation. Moreover, with respect to method of use patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method of use patents, the practice is common and this type of infringement is difficult to prevent or enforce. Consequently, we may not be able to prevent third parties from practicing our inventions in the United States or abroad.

Intellectual property rights of third parties could adversely affect our ability to commercialize our product(s) and product candidates, and we might be required to litigate or obtain licenses from third parties in order to develop, test or market our product(s) and product candidates.

Because our products and product candidates are still in early stages of development, testing or commercialization, and one or more features of the products or product candidates, or related technologies such as their manufacture, formulation, testing or use, may still change, we cannot be confident that we are aware of all third-party intellectual property that might be relevant to products that we eventually hope to commercialize. Furthermore, even if all aspects of our product(s) or product candidates, or of other technology, were known, it is possible that third-party intellectual property, which may or may not currently be public, could develop in a manner (for example, through issuance of additional patents) that could impede our ability to make or use relevant products or product candidates, or other technology. Various third-party competitors practice in relevant spaces, and may have issued patents, or patent applications that will issue as patents in the future, that will impede or preclude our ability to commercialize products. Furthermore, while U.S. patent laws provide a “safe harbor” to our clinical product candidates under 35 U.S.C. § 271(e) (1), which exempts from patent infringement activities related to pursuing FDA approval for a drug product, that exemption expires when an NDA or BLA is submitted. Accordingly, after such submission (including for certain formulations of our COVID-19 vaccine), the 271(e)(1) safe harbor may no longer provide the same level of protection from third party patent infringement claims for that product. We may become exposed to lawsuits from third parties who consider our COVID-19 vaccine to infringe their patents. More generally, given the uncertainty of clinical trials, we cannot be certain of the timing of their completion and it is possible that we might want to submit an NDA or BLA at a time when one or more relevant third-party patents is in force. Thus, it is possible that at the time that we commercialize our product candidates, one or

more third parties may have issued patent claims that cover such products or critical features of their production, testing or use. We may not be able to commercialize our products if patents issued to third parties or other third-party intellectual property rights cover, or may be alleged to cover, our products or elements thereof, or their methods of manufacture, testing or use at the time that we seek to commercialize them. In such cases, we may not be in a position to develop, test or commercialize product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, successfully design around their claims, or enter into a license agreement with the intellectual property right holder(s). Such litigation or licenses could be costly, licenses could not be available on commercially reasonable terms or at all, and design-around could be prohibitively expensive or impossible.

Additionally, with respect to our products, product candidates and related technologies that may play a role in addressing a pandemic or other public health emergency, it is unclear whether governments around the world will protect vaccine manufacturers for liability from infringement of third party intellectual property, at least during the period of such public health emergency. Thus, it is possible that third parties may assert intellectual property rights against us relating to our COVID-19 vaccine, and that we will not be successful in arguing that commercialization of our COVID-19 vaccine is exempted from infringement and/or liability for infringement (for example, under 35 U.S.C. § 271(e)(1), discussed above, or under the Public Readiness and Emergency Preparedness Act, or the PREP Act, etc.). Furthermore, even if such commercialization was deemed protected from infringement during the period of the pandemic crisis, now that various global and U.S. agencies have declared an end to the global COVID-19 public health emergency, any such exemption may be terminated so that continuing commercialization could expose us to liability, and might even be precluded if third party(ies) who hold relevant intellectual property rights are able to secure injunction(s) or are unwilling to license to us on commercially feasible terms.

It is also possible that we have failed to identify relevant third-party patents that cover, or applications that will mature into patents that cover, one or more aspects of our platform or product(s) and product candidates. Given that, in most jurisdictions, a patent application is confidential when initially filed, and typically remains so until it is published about 18 months after the initial filing, it may not be possible for us to identify certain relevant filings in time to avoid using the technology that they claim. Additionally, the claims of pending patent applications can, subject to certain limitations, be amended over time, so that even patent applications whose claims did not cover our products or activities when published could be amended to cover one or more aspects of our platform or product candidates over time, and we might not be aware that such amendment had been made.

We may be involved in lawsuits or other legal proceedings to protect or enforce our intellectual property or the intellectual property of our licensors, or to defend against third-party claims that we infringe, misappropriate or otherwise violate such third party's intellectual property, each of which could be expensive, time consuming and unsuccessful.

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, ex parte reexaminations, post-grant review, and inter partes review proceedings before the USPTO and corresponding European and other non-U.S. patent offices.

Competitors and other third parties may infringe, misappropriate or otherwise violate our intellectual property rights or those of our licensors. To prevent infringement, misappropriation or other unauthorized use, we may be required to file claims, which can be expensive and time-consuming. In certain instances, we have instituted and may in the future institute inter partes review proceedings against issued U.S. patents and opposition proceedings against European patents owned by third parties. We have a number of opposition proceedings ongoing at the European Patent Office against third-party patents related to mRNA technologies; also, multiple oppositions have been filed against our EP patent number 2714071, which relates to our iNeST product candidates, and whose claims recite steps relating to neoantigen selection. While the claims of our issued EP patent 2714071 were upheld after opposition, there is currently an appeal pending. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products, product candidates and services may be subject to claims of infringement of the patent rights of third parties.

In addition, in a patent infringement proceeding, our owned or in-licensed patents may be challenged and a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product(s) and/or product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including novelty, non-obviousness, enablement or written description. Grounds for an

unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in ex-U.S. patent offices and may result in the revocation, cancellation or amendment of any ex-U.S. patents we hold in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we could lose at least part, and perhaps all, of the patent protection on a product and/or product candidate. Such a loss of patent protection would have a material adverse impact on our competitive position, business, financial conditions, results of operations and prospects.

Third parties, including our competitors to non-practicing entities or patent assertion entities, may assert that we are employing their intellectual property and other proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, testing, methods of manufacture or methods for treatment related to the use, development, testing, manufacture or commercialization of our COVID-19 vaccine or product candidates. For example, BioNTech SE and certain of our wholly owned subsidiaries are defendants in litigations initiated by CureVac SE, Alnylam Pharmaceuticals, Inc., ModernaTX, Inc., Arbutus Biopharma Corp. and Genevant Sciences GmbH regarding *Comirnaty*. See “Legal Proceedings.” As patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product(s) and/or product candidates may infringe. In addition, third parties may obtain patents in the future and claim that our technologies infringe upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the testing or manufacturing processes of any of our product(s) and/or product candidates, any molecules formed during the testing and manufacturing processes or any final product itself, the holders of any such patents may obtain injunctive or other equitable relief, which could effectively block our ability to develop, test and commercialize such product and/or product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for testing or manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop, test and commercialize the applicable product and/or product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms, or at all, or may be non-exclusive.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same intellectual property and technology. Our defense of litigation, interference, derivation or similar proceedings may fail and, even if successful, may result in substantial costs and distract our management, technical personnel and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds we need to continue our clinical trials and research programs, to license necessary technology from third parties or to enter into development or manufacturing collaborations that would help us bring our product(s) and/or product candidates to market.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our management, technical personnel and other employees from their normal responsibilities. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of our competitors may be able to sustain the costs of such proceedings more effectively than we can because of their greater resources in one or more aspects, or for other reasons. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys’ fees for willful infringement, pay royalties, redesign our infringing products, or obtain one or more licenses from third parties, which may not be made available on commercially favorable terms, if at all, or may require substantial time and expense.

Such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same intellectual property and technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and product(s) and/or product candidates, which could limit our ability to generate revenues or achieve or maintain profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Moreover, certain of our collaborations provide, and we expect additional

collaborations to provide, that royalties payable to us for licenses to our intellectual property may be offset by amounts paid by our collaborators to third parties for licenses to such third parties' intellectual property in the relevant fields, which could result in significant reductions in our revenues from products developed through collaborations.

In addition, in connection with certain license and collaboration agreements, we have agreed to indemnify certain third parties for certain costs incurred in connection with litigation relating to intellectual property rights or the subject matter of the agreements. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any litigation or other intellectual property proceedings. If securities analysts or investors perceive these results to be negative, the price of the ADSs representing our ordinary shares could decline.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on patents and applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents or applications. We have systems in place to remind us to pay these fees and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies; however, we cannot guarantee that we will successfully pay these fees. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our in-licensed intellectual property, and we cannot guarantee that they will do so. In such an event, our competitors might be able to enter the market with similar or identical products or technology, and this would have a material adverse impact on our business, financial condition, results of operations and prospects.

Changes in patent law in the United States or in other countries could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on our intellectual property rights, particularly patents that we own and in-license. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and therefore obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. Moreover, there are periodic changes in patent law. For example, after March 2013, under the America Invents Act, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that have affected the way patent applications are prosecuted and also affect patent litigation. Such legislation and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, decisions by courts and governmental bodies in the United States and other jurisdictions may affect the value of patent applications, issued patents or other intellectual property that we own or in-license. For example, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, the USPTO and other administrative agencies, and their equivalents in other jurisdictions, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to obtain, maintain, protect, defend or enforce our intellectual property in the future.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for some of our technology, product(s) and product candidates, we also seek to rely on trade secret protection and confidentiality agreements to maintain our competitive position and protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery development, testing, manufacturing and commercialization processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets and know-how may be difficult to protect.

We seek to protect these trade secrets, know-how and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants and require all of our employees and key consultants who have access to our trade secrets, proprietary know-how, information or technology to enter into confidentiality agreements. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. To the extent we become involved in litigation that may require discovery of our trade secrets, know-how and other proprietary technology, we seek to secure protective orders from the court that bind the parties with access to the discovered information. Despite our best efforts, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Any of these parties who may have access to our trade secrets, know-how and other proprietary technology may breach such agreements or orders. For example, a former employee of our COVID-19 vaccine collaborator, Pfizer, has reportedly misappropriated trade secrets on our COVID-19 vaccine. We may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret or know-how is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets and know-how. In addition, we cannot be certain that our proprietary technical information and related confidential documents that we have shared with our collaborators and/or have submitted to governmental agencies including regulatory agencies for evaluation and supervision of pharmaceutical products will be kept confidential. For example, certain documents relating to our COVID-19 vaccine were unlawfully accessed after a cyberattack on the EMA in December 2020. If any of our trade secrets or know-how were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, financial condition and prospects.

We may be subject to claims that we have wrongfully hired an employee from a competitor, or that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, including alleged trade secrets of their former employers.

We have received confidential and proprietary information from third parties in the course of our research and other collaborations with others in the industry, academic institutions and other third parties. In addition, many of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, independent contractors and advisors do not use the confidential or proprietary information, trade secrets or know-how of others in their work for us, we may be subject to claims that we have inadvertently or otherwise used or disclosed confidential or proprietary information, trade secrets or know-how of these third parties, or that our employees, consultants, independent contractors or advisors have inadvertently or otherwise used or disclosed confidential information, trade secrets or know-how of such individual's current or former employer. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management, technical personnel and other employees. Claims that we or our employees, consultants or advisors have misappropriated the confidential or proprietary information, trade secrets or know-how of third parties could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

In the future, we may be subject to claims that current or former employees, consultants, independent contractors, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees, consultants, independent contractors, collaborators and other third parties who may be involved in the conception, development or reduction to practice of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives, develops or reduces to practice such intellectual property that we regard as our own. In addition, certain such agreements, even if successfully executed may distribute ownership or control of intellectual property rights between or among parties, for example based on subject matter, relationship to other intellectual property, and/or one or more aspects of development of the intellectual property; after the agreements are in place disputes may arise over such distribution principles or over proper treatment of particular developed intellectual property in accordance with them. Disagreements may be difficult or impossible to resolve, may be expensive to address, and may result in our failing to secure or maintain ownership in or control of intellectual property necessary or important to our business.

The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached. For example, we may have inventorship or ownership disputes arise from conflicting obligations of employees, consultants, independent contractors, collaborators or other third parties who are involved in developing and commercializing our product(s) and/or product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, operating results and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management, technical personnel and other employees.

Furthermore, the laws of some other countries do not protect intellectual property and other proprietary rights or establish ownership of inventions to the same extent or in the same manner as the U.S. laws. A majority of our employees work in Germany and are subject to German employment law. Ideas, developments, discoveries and inventions made by such employees are subject to the provisions of the German Act on Employees' Inventions, which regulates the ownership of, and compensation for, inventions made by employees. We face the risk that disputes can occur between us and our employees or former employees pertaining to alleged non-adherence to the provisions of this act that may be costly to defend and take up our management's, technical personnel's and other employees' time and efforts whether we prevail or fail in any such dispute. There is a risk that the compensation we provided to employees who assign patents to us may be deemed to be insufficient and we may be required under German law to increase the compensation due to such employees for the use of the patents. In those cases, where employees' rights have not been assigned to us, we may need to pay compensation for the use of those patents. If we are required to pay additional compensation or face other disputes under the German Act on Employees' Inventions, our business, results of operations and financial condition could be adversely affected.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on product(s) and/or product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States, particularly those in Asia, including China, can be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws in Germany and the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States to the same extent as within the United States, or from selling or importing products made using our inventions in and to the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own product candidates and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product(s) and/or product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions, particularly outside of Europe and the United States. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the

infringement, misappropriation or other violation of our patents and other intellectual property or development, testing, marketing and commercialization of competing products in violation of our owned or in-licensed intellectual property and other proprietary rights generally. Proceedings to enforce our intellectual property rights in such jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or in-license. In particular, the validity, enforceability and scope of protection of intellectual property in China, where we derive net sales and maintain collaboration partnership including licensing, are still evolving and historically, have not protected and may not protect in the future, intellectual property rights to the same extent as laws developed in Europe, including Germany, and the United States. Consequently, the time required to enforce our intellectual property rights in the legal regime of China may be lengthy and delay our recovery.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours or collaborators may fail to use our trade names or trademarks appropriately or at all, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors and collaborators. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse or failure to use of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks, and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, know-how, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make COVID-19 vaccines or therapies, and/or personalized cancer immunotherapies that are similar to our COVID-19 vaccine and/or any product candidates we may develop and commercialize or utilize similar technologies that are not covered by the claims of the patents that we now or may in the future own or have exclusively in-licensed;
- we, our co-owners or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively in-licensed;
- we, our co-owners or our licensors or future collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;

- it is possible that our pending patent applications or those that we may own or in-license in the future will not lead to issued patents;
- claims of issued patents that we own or have exclusively in-licensed may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research, development, testing or commercialization activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Government Regulation

We may not be able to develop or obtain approval for companion diagnostics required for commercialization of some of our product candidates.

Administration of some of our product candidates may require the use of immuno-assays and bioinformatic tools in which patients are screened for optimal target antigens of our product candidates. If safe and effective use of a biologic product depends on an in vitro diagnostic, then the FDA generally requires approval or clearance of the diagnostic, known as a companion diagnostic, concurrently with approval of the therapeutic product. To date, the FDA has generally required in vitro companion diagnostics intended to select the patients who will respond to cancer treatment to obtain a pre-market approval, or PMA, for that diagnostic, which can take up to several years, simultaneously with approval of the biologic product. Similarly, in the European Union, an in vitro companion diagnostic may be placed on the market only if it conforms to certain “essential requirements” and bears the Conformité Européene Mark, or CE Mark. The conformity assessment process to obtain the CE Mark can be lengthy and we may fail to demonstrate such conformity. Further, the applicable regulatory framework for in vitro diagnostics in the EU changed in May 2022 when a new EU regulation with stricter regulatory requirements for in vitro diagnostics became applicable.

For our individualized immunotherapy candidates, the FDA and comparable regulatory authorities outside of the United States may require the development and regulatory approval of a companion diagnostic assay as a condition to approval. The FDA may require PMA supplemental approvals for use of that same companion diagnostic as a condition of approval of additional individualized therapeutic candidates. We do not have experience or capabilities in developing or commercializing companion diagnostics and plan to rely in large part on third parties to perform these functions. Companion diagnostic assays are subject to regulation by the FDA and other comparable regulatory authorities in other jurisdictions as medical devices and require separate regulatory approval prior to the use of such diagnostic assays with our individualized therapeutic candidates. If we, or any third parties that we engage to assist us, are unable to successfully develop companion diagnostic assays for use with our individualized therapeutic candidates, or are unable to obtain regulatory approval or experience delays in either development or obtaining regulatory approval, we may be unable to identify patients with the specific profile targeted by our product candidates for enrollment in our clinical trials. Accordingly, further investment may be required to further develop or obtain the required regulatory approval for the relevant companion diagnostic assay, which would delay or substantially impact our ability to conduct additional clinical trials or obtain regulatory approval.

Because we are developing some of our product candidates for the treatment of diseases in which there is little clinical experience and, in some cases, using new endpoints or methodologies, the FDA, the EMA or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results.

There may not be pharmacologic therapies approved to treat the underlying causes of many diseases that we may address in the future. For instance, we and our collaborators are applying our technology to develop therapeutics in indications such as certain rare diseases, including some for which no or few clinical trials have been attempted. As a result, any future design and conduct of clinical trials of product candidates for the treatment of certain rare diseases may take longer, be more costly, or be less effective as part of the novelty of development in these diseases. Even if we decide to conduct clinical trials and the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we

may not achieve the pre-specified endpoint to a degree of statistical significance in any pivotal or other clinical trials we or our collaborators may conduct for our programs. Further, even if we do achieve the pre-specified criteria, our trials may produce results that are unpredictable or inconsistent with the results of the more traditional efficacy endpoints in the trial. The FDA also could give overriding weight to other efficacy endpoints over a primary endpoint, even if we achieve statistically significant results on that endpoint, if we do not do so on our secondary efficacy endpoints. The FDA also weighs the benefits of a product against its risks and the FDA may view the efficacy results in the context of safety as not being supportive of licensure. Other regulatory authorities in Europe and other jurisdictions may make similar findings with respect to these endpoints.

The FDA, the EMA or other comparable regulatory authorities may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.

If the results of our clinical trials are sufficiently compelling, we or our collaborators intend to discuss with the FDA and regulatory authorities in other countries the submission of a BLA or respective applications in other countries for our product candidates. However, we do not have any agreement or guidance from the FDA that our regulatory development plans will be sufficient for submission of a BLA for any of our product candidates. The FDA, the EMA or other regulatory agencies may grant accelerated approval for our product candidates and, as a condition for accelerated approval, the FDA, the EMA or other regulatory agencies may require a sponsor of a drug or biologic receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA, the EMA or other regulatory agencies that are more accelerated than those available for regular approvals. In addition, the standard of care may change with the approval of new products in the same indications that we are studying. This may result in the FDA, the EMA or other regulatory agencies requesting additional studies to show that our product candidate is superior to the new products.

Our clinical trial results may also not support approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, the EMA or comparable regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or comparable regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA or comparable regulatory authorities for approval, including due to the heterogeneity of patient populations;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA, the EMA or comparable regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA, the EMA or comparable regulatory authorities to support the submission of a BLA or other comparable submissions or to obtain regulatory approval in the United States or elsewhere;
- the FDA, the EMA or comparable regulatory authorities will inspect our manufacturing facilities and may not approve our facilities or our manufacturing processes and controls; and
- the approval policies or regulations of the FDA, the EMA or comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We may not be able to file INDs with the FDA, clinical trial applications with the competent authorities of the member states of the European Union or similar applications with other comparable regulatory authorities to commence additional clinical trials on the timelines we expect, and even if we are able to, one or more of these regulatory authorities may not permit us to proceed.

The timing of filing on our product candidates is dependent on further preclinical, clinical and manufacturing success. We cannot be sure that submission of an IND or IND amendment with the FDA, a clinical trial application with the regulatory authorities of the EU member states or similar application with other comparable regulatory authorities will result in the FDA, the regulatory authorities of the EU member states or any comparable regulatory authority allowing testing and clinical trials to begin, or that, once begun, issues will not arise that result in the suspension or termination of

such clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, clinical trial application or similar applications, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

We may seek orphan drug designation for some or all of our product candidates across various indications, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.

Our strategy includes filing for orphan drug designation where available for our product candidates. Under the U.S. Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population of 200,000 or greater in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full new drug application or a BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the original manufacturer is unable to assure sufficient product quantity. Similar rules apply in the European Union with respect to drugs or biologics designated as orphan medicinal products.

In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not protect the product effectively from competition because different drugs with different active moieties may receive and be approved for the same condition, and only the first applicant to receive approval will receive the benefits of marketing exclusivity. Even after an orphan-designated product is approved, the FDA can subsequently approve a later drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective, or makes a major contribution to patient care. Similar considerations apply in the European Union with respect to drugs or biologics designated as orphan medicinal products. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek orphan drug designation for our product candidates, we may never receive such designations.

We may seek breakthrough therapy or fast-track designation for one or more of our product candidates, but we may not receive such designations. Even if we do, it may not lead to a faster development or regulatory review or approval process, and it may not increase the likelihood that such product candidates will receive marketing approval.

We may seek a breakthrough therapy designation in the United States for one or more of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Designation as a breakthrough therapy is at the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a drug may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened.

We may also seek Fast Track Designation in the United States for some of our product candidates. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address significant unmet medical needs for this condition, the drug sponsor may apply for Fast Track Designation. The FDA has

broad discretion whether or not to grant this designation, and even if we believe a particular product candidate is eligible for this designation, we cannot be sure that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track Designation alone does not guarantee qualification for the FDA's priority review procedures.

We expect some of the product candidates we develop will be regulated as biologics in the United States and therefore they may be subject to competition from biosimilars approved through an abbreviated regulatory pathway.

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved.

During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for a 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Some of our product candidates are classified as gene therapies by the FDA and the EMA, and the FDA has indicated that our product candidates will be reviewed within its Center for Biologics Evaluation and Research, or CBER. Even though our mRNA product candidates are designed to have a different mechanism of action from gene therapies, the association of our product candidates with gene therapies could result in increased regulatory burdens, impair the reputation of our product candidates, or negatively impact our platform or our business.

There have been few approvals of gene therapy products in the United States and other jurisdictions, and there have been well-reported significant adverse events associated with their testing and use. Gene therapy products have the effect of introducing new DNA and potentially irreversibly changing the DNA in a cell. In contrast, mRNA is highly unlikely to localize to the nucleus, be reverse transcribed or integrated into the genome. Consequently, we expect that our products or product candidates will have a different potential side effect profile from gene therapies because they lack risks associated with altering cell DNA irreversibly. Further, we may avail ourselves of ways of mitigating side effects in developing our products and product candidates to address safety concerns that are not available to other products or product candidates classified as gene therapies, such as lowering the dose of our products or product candidates during repeat dosing or stopping treatment to potentially ameliorate undesirable side effects.

Regulatory requirements governing gene and cell therapy products have evolved and may continue to change in the future, and the implications for mRNA-based therapies is unknown. For example, the FDA has established the Office of Tissues and Advanced Therapies within CBER to consolidate the review of gene therapy and related products, and convenes the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. In the European Union, mRNA has been characterized as a gene therapy medicinal product. In certain countries, mRNA therapies have not yet been classified or any such classification is not known to us. Notwithstanding the differences between our mRNA product candidates and gene therapies, the classification of some of our mRNA product candidates as gene therapies in the United States, the European Union and potentially other countries could adversely impact our ability to develop our product candidates, and could negatively impact our platform and our business. For instance, a potential future clinical hold on gene therapy products across the field due to risks associated with altering cell DNA irreversibly could apply to our mRNA product candidates irrespective of the mechanistic differences between gene therapies and mRNA.

Adverse events reported with respect to gene therapies or genome editing therapies could adversely impact one or more of our programs. Although our mRNA product candidates are designed not to make any permanent changes to cell DNA, regulatory agencies or others could believe that adverse effects of gene therapy products caused by introducing new DNA and irreversibly changing the DNA in a cell could also be a risk for our approved mRNA products or investigational therapies, and as a result may delay one or more of our trials or impose additional testing for long-term side effects. Any new requirements and guidelines promulgated by regulatory review agencies may have a negative effect on our business by lengthening the regulatory review process, requiring us to perform additional or larger studies, or increasing our development costs, any of which could lead to changes in regulatory positions and interpretations, delay or prevent advancement or approval and commercialization of our product candidates or lead to significant post-approval studies, limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and advisory committees and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of some or all of our product candidates.

The regulatory landscape that will govern our product candidates is uncertain. Regulations relating to more established gene therapy and cell therapy products are still developing, and changes in regulatory requirements could result in delays or discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval.

The regulatory requirements to which our product candidates will be subject are not entirely clear. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. For example, regulatory requirements governing gene therapy products and cell therapy products have changed frequently and may continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical study, even if the FDA has reviewed the study and approved its initiation. Conversely, the FDA can place an IND application on clinical hold even if such other entities have provided a favorable review. Furthermore, gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at the institution participating in the clinical trial. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates.

Complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. For example, in the European Union, a special committee called the Committee for Advanced Therapies, or CAT, was established within the EMA in accordance with Regulation (EC) No 1394/2007 on advanced-therapy medicinal products, or ATMPs, to assess the quality, safety and efficacy of ATMPs, and to follow scientific developments in the field. ATMPs include gene therapy products as well as somatic cell therapy products and tissue engineered products.

These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As the regulatory landscape for our CAR-T-cell immunotherapy product candidates is new, we may face even more cumbersome and complex regulations than those emerging for gene therapy products and cell therapy products. Furthermore, even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies.

Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product sales revenue to maintain our business.

We may be unable to obtain regulatory approval for our product candidates under applicable international regulatory requirements.

The denial or delay of such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

Approval by the FDA in the United States, if obtained, does not ensure approval by regulatory authorities in other countries or jurisdictions. In order to market our products or product candidates in any other jurisdiction, we must establish

and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding safety and efficacy. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking regulatory approval in other jurisdictions could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. The European Union and other jurisdictions' regulatory approval processes involve all of the risks associated with the FDA approval. If we fail to comply with regulatory requirements in certain markets or to obtain and maintain required approvals, or if regulatory approvals in certain markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

Certain jurisdictions may have submission requirements for drug clinical trial and marketing applications that require us or our partners to submit substantial detailed materials related to non-clinical and clinical development and manufacturing and quality control to drug regulators or testing laboratories. This can include executed batch records for the production of biological products or other records or documents that set forth detailed information about the manufacturing process. If these records are disclosed, lost, or diverted to third parties or competitors during the application preparation process, this could negatively affect our ability to protect our intellectual property.

Our partners in different countries are subject to local regulatory requirements on the manufacturing and distribution of drugs and the implementation of clinical and non-clinical research. These include but are not limited to good manufacturing, distribution, laboratory, and clinical practice rules. If these companies do not comply with applicable standards, they could become the subjects of investigations and enforcement, including orders to cease the activities pending remediation that is acceptable to the government. Such an order or other similar enforcement could interfere with our clinical development activities both in that jurisdiction and others, if it impacts supply or the quality and transfer of data.

A third-party investigational product candidate used in combination with our product candidates may be unable to obtain regulatory approval, which may delay commercialization of our product candidates.

We are developing several of our product candidates to be used in combination with our and third-party product candidates. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing products, we would continue to be subject to the risks that the FDA, the EMA or comparable regulatory authorities in other jurisdictions could revoke approval of the product used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing products. If the products or product candidates we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA, the EMA or comparable regulatory authorities in other jurisdictions may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially. We also plan to evaluate current and future product candidates in combination with one or more product candidates that have not yet been approved for marketing by the FDA, the EMA or comparable regulatory authorities in other jurisdictions. We will not be able to market any product candidate we develop in combination with an unapproved product candidate if that unapproved product candidate does not ultimately obtain marketing approval. In addition, unapproved product candidates face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA, EMA or comparable regulatory authority approval.

If the FDA, the EMA or comparable regulatory authorities in other jurisdictions do not approve these other product candidates or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the products or product candidates we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval of or market any product candidate we develop.

Our COVID-19 vaccine and any other product candidates for which we receive approval or emergency use authorization are subject to continuing regulatory oversight, and we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. We may be subject to penalties if

we fail to comply with regulatory requirements or experience unanticipated problems with our products or product candidates.

Our COVID-19 vaccine and any other product candidates for which we receive approval or emergency use authorization are subject to continuing regulatory oversight, including the review of additional safety information, and the applicable regulatory authority may still impose significant restrictions on the indicated uses or marketing of our product or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Similar requirements apply to holders of (conditional) approvals in other countries. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. In other countries, advertising and promotional material may be subject to similar rules.

If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval or revoke a license;
- suspend any ongoing clinical studies;
- refuse to approve a pending BLA (or comparable approval) or supplements to a BLA (or comparable approval) submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any approved products and generate revenues.

If any of our products or product candidates cause undesirable side effects, it could delay or prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences following any potential marketing approval. Products or product candidates we may develop may be associated with an adverse immune response or other serious adverse events, undesirable side effects or unexpected characteristics. In addition to serious adverse events or side effects caused by any of our products or product candidates, the administration process or related procedures also can cause undesirable side effects. If any such events occur, the clinical trials of any of our product candidates could be suspended or terminated.

If in the future we are unable to demonstrate that such adverse events were caused by factors other than our product candidate, the FDA, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any of our product candidates for any or all targeted indications. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled trial participants to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any of our product candidates, the commercial prospects of such product candidates, if approved, may be harmed and our ability to generate product sale revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to identify and develop product candidates, and may harm our business, financial condition, result of operations and prospects significantly.

Additionally, following regulatory approval of a product candidate, the FDA or other regulatory authority could require us to adopt a REMS or a risk management plan, or RMP, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, extensive patient monitoring, or distribution systems and processes that are highly controlled, restrictive, and more costly than what is typical for the industry.

Furthermore, if we or others later identify undesirable side effects caused by any product that we develop, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals or revoke licenses of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way a product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients and their children; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any products we may identify and develop and could have a material adverse effect on our business, financial condition, results of operations and prospects.

Upon the successful approval of a product candidate, we will continue to face significant regulatory oversight of its manufacturing and distribution. Product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP and adherence to commitments made in the BLA or comparable approval. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and other healthcare laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

We may be subject to additional healthcare regulation and enforcement by the U.S. federal government and by authorities in the United States, the European Union and other jurisdictions in which we conduct our business. Our operations may be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations, including, without limitation, the federal Health Care Program Anti-Kickback Statute, the federal civil and criminal False Claims Act, and the Physician Payments Sunshine Act and regulations. Many states and other jurisdictions have similar laws and regulations, some of which may be broader in scope. These laws will impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws enacted by both the federal government and the states in which we conduct our business. The laws that will affect our operations include, but are not limited to the following:

- The U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers, and formulary managers on the other. The ACA amends the intent requirement of the federal Anti-Kickback Statute to provide that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it;
- The U.S. federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval from Medicare, Medicaid or other government payors. The ACA provides, and recent government cases against pharmaceutical and medical device manufacturers support, the view that federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may implicate the False Claims Act;
- The U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private);
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers;

- The U.S. Federal Food, Drug, and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- The U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;
- Federal transparency laws, including the federal Physician Payment Sunshine Act, which require disclosure of payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;
- U.S. state law equivalents of each of the above federal laws, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances which are also applicable to us, and many of them differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances;
- The U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents, as well as non-U.S. companies that are registered with the SEC, from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; and
- Similar statutes, healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Due to the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union member states and other jurisdictions, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization or the regulatory authorities of the individual EU member states. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

We are subject to certain anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as "trade laws," prohibit companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors and other collaborators from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of trade laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, intellectual property (including patents) and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents or collaborators, even if we do not explicitly authorize or have prior knowledge of such activities.

We are subject to stringent privacy laws, information security policies and contractual obligations governing the use, processing, and cross-border transfer of personal information and our data privacy and security practices.

We receive, generate and store significant and increasing volumes of sensitive information, such as employee, personal and patient data.

We are subject to a variety of local, state, national and international laws, directives and regulations that apply to the collection, use, storage, retention, protection, disclosure, transfer and other processing of personal data, collectively referred to as “data processing”, in the different jurisdictions in which we operate, including comprehensive regulatory systems in the United States and Europe. Legal requirements relating to data processing continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement, sanctions and increased costs of compliance.

Compliance with U.S. and international data protection laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Moreover, complying with these various laws could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals’ privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition and results of operations.

The collection and use of personal data in the European Union had previously been governed by the provisions of the EU Data Protection Directive, which EU member states were required to implement. While the Data Protection Directive did not apply to organizations based outside the European Union, the GDPR has expanded its reach to include any business, regardless of its location, that targets goods or services to residents in the European Union or that “monitors” their behavior in the European Union. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for “sensitive information” which includes health and genetic information of patients residing in the European Union. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States and other countries. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

Since we are located in the European Union, we are subject to the GDPR. Additionally, as the GDPR applies extraterritorially, we are also subject to the GDPR even where our data processing activities occur outside of the European Union if such activities involve the personal data of individuals located in the European Union and the above-mentioned applicable law triggers apply. GDPR regulations have imposed additional responsibility and liability in relation to the personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules. This may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations and prospects.

Other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules and regulations, which could increase our compliance costs and the risks associated with non-compliance. In particular, in China, where some of our clinical data are originated, the cybersecurity, data privacy, data protection, or other data-related laws and regulations, including the Human Genetic Resources Regulation (which now only regulates transfer human genetic data generated in clinical research to foreign or foreign controlled parties), are relatively new and evolving, and their interpretation and application may be uncertain. In the United States, we may be subject to restrictions and requirements under the Executive Order on Preventing Access to Americans’ Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern, signed on February 28, 2024. Practices regarding the collection, use, storage, transmission and security of personal information by companies have also been subject to increasing regulatory focus. As such, we cannot assure you that we will be compliant with such new regulations in all respects, and we may be ordered to rectify and terminate any actions that are deemed illegal by the government authorities and become subject to fines and other government sanctions, which may materially and adversely affect our business, financial condition, and results of operations. In addition, the uncertainties regarding further interpretation and implementation of these laws and regulations may adversely affect the secure storage of documented work as well as the cross-border transfer of important data and personal information originated from our clinical trial activities, which are critical to the development of our pipelines.

We cannot guarantee that we are, or will be, in compliance with all applicable international regulations as they are enforced now or as they evolve. For example, our privacy policies may be insufficient to protect any personal information

we collect, or may not comply with applicable laws, in which case we may be subject to regulatory enforcement actions, lawsuits or reputational damage, all of which may adversely affect our business. There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with the GDPR and other international data protection regulations, especially with regard to clinical trial activities. For example, it is not clear if the authorities will conduct random audits of companies doing business in the European Union, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated, as enforcement practices vary from country to country. Enforcement uncertainty and the costs associated with ensuring GDPR compliance may be onerous and adversely affect our business, financial condition, results of operations and prospects. If we fail to comply with the GDPR and the applicable national data protection laws of the EU member states, or if regulators assert we have failed to comply with these laws, it may lead to regulatory enforcement actions, which can result in monetary penalties of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. If any of these events were to occur, our business and financial results could be significantly disrupted and adversely affected.

Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, as well as regulatory penalties. In many jurisdictions, there are legal requirements to provide notice of breaches to affected individuals and/or regulators in certain circumstances. Such a notice could harm our reputation and our ability to compete. Regulators may also have the discretion to impose penalties without attempting to resolve violations through informal means. Although we have implemented security measures to prevent unauthorized access to patient data, such data is currently accessible through multiple channels, and there is no guarantee we can protect our data from breach. Unauthorized access, loss or dissemination could also damage our reputation or disrupt our operations, including our ability to conduct our analyses, deliver test results, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business.

If we or our third-party suppliers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also may produce hazardous waste products. We generally anticipate contracting with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Risks Related to Ownership of the ADSs

We have experienced and may continue to experience significant volatility in the market price of the ADSs representing our ordinary shares.

Biopharmaceutical companies such as BioNTech SE that are developing potential therapeutics and vaccines to combat COVID-19, as well as conducting mRNA-based research in oncology and infectious disease more generally, have experienced significant volatility in the price of their securities upon publication of preclinical and clinical data as well as news about their development programs and commercialization activities. For example, during 2023, the closing sales price of the ADSs representing our ordinary shares on the Nasdaq Global Select Market ranged from \$88.00 to \$156.28, with significant volatility occurring, for example, shortly after announcements by us or others related to regulatory matters, to our COVID-19 vaccine, to other COVID-19 vaccines, to development and commercialization pipelines in oncology and infectious disease, and to our transactions with third parties. Additionally, we have observed the trading price of the ADSs respond significantly to news and statements by us, government agencies, other vaccine developers, financial analysts or others relating to our business as well as to other COVID-19 vaccines and COVID-19 therapeutics and the spread of COVID-19 generally, even in cases in which we believe the news does not affect our business or vaccine specifically. Given the attention being paid to COVID-19 worldwide and the public scrutiny of COVID-19 development and commercialization announcements, and given that our COVID-19 vaccine is currently among the primary vaccines being used worldwide, any news regarding manufacturing, supply and distribution of our COVID-19 vaccine or unanticipated side effects of our COVID-19 vaccine, whether or not accurate, will attract significant attention and scrutiny and, as a result, the price of the ADSs representing our ordinary shares likely will continue to be volatile. In addition, volatility in the overall market and in the market price of a particular company's securities can result in securities litigation, including shareholder class action lawsuits. Any securities litigation can result in substantial costs and a diversion of our management's attention and resources.

Acquisitions, joint ventures and collaborations may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks. We may not realize the benefits of these acquisitions, joint ventures or collaborations.

We may evaluate various acquisitions and collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition, joint venture or collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and

- our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may utilize our cash, issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. For example, in July 2023, we acquired InstaDeep, a leading global technology company in the field of AI and machine learning, for upfront consideration of cash and BioNTech shares, and potential future milestone payments. Although we believe that AI and machine learning technology has the potential to accelerate the development of therapeutic programs and further optimize manufacturing and supply chain processes, it is possible that our use of the acquired technology will not achieve the desired results, and that we will not be able to retain and grow InstaDeep's business around the world. If demand for the services developed by InstaDeep does not continue, or if we are unable to improve our AI and machine learning technology in a timely, effective and competitive manner, we may not be able realize the expected outcomes from the InstaDeep acquisition. There is no guarantee that we will realize any anticipated benefits of this or future acquisitions, or that the diversification of our business through acquired technology or products will be successful.

Moreover, we may not be able to locate suitable acquisition or collaboration opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Our Articles of Association designate specific courts in the United States as the exclusive forum for certain U.S. litigation that may be initiated by our shareholders, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us.

Our Articles of Association provide that the United States District Court for the Southern District of New York shall be the competent court of jurisdiction for the resolution of any litigation on the grounds of or in connection with U.S. federal or state capital market laws. In the absence of these provisions, under the Securities Act of 1933, as amended, or the Securities Act, U.S. federal and state courts have been found to have concurrent jurisdiction over suits brought to enforce duties or liabilities created by the Securities Act. This choice of forum provision will not apply to suits brought to enforce duties or liabilities created by the Securities Exchange Act of 1934, as amended, which already provides that such federal district courts have exclusive jurisdictions over such suits.

The choice of forum provision contained in our Articles of Association may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our executive officers, directors, or other employees, or impose additional litigation costs on shareholders in pursuing any such claims, particularly if the shareholders do not reside in or near the state of New York, which may discourage such lawsuits. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other U.S. or German courts will enforce our choice of forum provision. The enforceability of similar choice of forum provisions in other companies' governing documents has been challenged in recent legal proceedings, and it is possible that a court in the relevant jurisdictions with respect to us could find the choice of forum provision contained our Articles of Association to be inapplicable or unenforceable. If the relevant court were to find the choice of forum provision contained in our articles of association to be inapplicable or unenforceable, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition and operating results. The choice of forum provision may also impose additional litigation costs on shareholders who assert that the provision is not enforceable or invalid. The United States District Court for the Southern District of New York may also reach different judgments or results than would other courts, including courts where a shareholder considering a U.S.-based action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our shareholders.

Holders of the ADSs may not be able to participate in any future preemptive subscription rights issues or elect to receive dividends in shares, which may cause additional dilution to their holdings.

Under German law, the existing shareholders of a company generally have a preemptive right in proportion to the amount of shares they hold in connection with any issuance of ordinary shares, convertible bonds, bonds with warrants, profit participation rights and participating bonds. However, our shareholders in a shareholders' meeting may vote, by a majority representing at least three-quarters of the share capital represented at the meeting, to waive this preemptive right provided that, from the company's perspective, there exists good and objective cause for such waiver.

The deposit agreement provides that the depositary need not make rights available to you unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from

registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our future rights offerings and may experience dilution in their holdings. For example, ADS holders were unable to participate in our summer 2020 rights offering. In addition, if the depositary is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case you will receive no value for these rights.

The amount and frequency of our dividends and ADS repurchases may fluctuate.

The amount, timing and execution of any ADS repurchase program we conduct in the future and the amount and timing of any dividends we pay may fluctuate based on our priorities for the use of cash for other purposes, and any ADS repurchases would be subject to the parameters contained in the applicable repurchase plan. These purposes may include operational spending, capital spending, acquisitions and repayment of debt. Additionally, we may choose to repurchase ADSs so that such ADSs may be used to settle outstanding and future equity awards granted to our employees. Changes in cash flows, tax laws and the price of the ADSs could also impact any ADS repurchase program. Additionally, we may enter into a Rule 10b5-1 trading plan governing the repurchases, and if we do, we would have no discretion over the particular purchases made and would only be able to set minimum price floors and maximum ADS count ceilings.

Our principal shareholders and management own a significant percentage of our ordinary shares and will be able to exert significant control over matters subject to shareholder approval.

Our executive officers, directors, five percent shareholders, and their affiliates beneficially own a majority of our ordinary shares (including ordinary shares represented by ADSs) as of December 31, 2023, and will have the ability to influence us through their ownership positions. For example, these shareholders, acting together, may be able to exert significant influence over matters such as elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our ordinary shares that shareholders may believe are in their best interest. Such insiders may also act in concert to waive rights to participate in rights offerings, as was done in our summer 2020 rights offering, which would have the effect of permitting the ADSs or shares underlying such waived rights to be offered to the public in an underwritten offering without contravening German law pricing requirements.

The large number of shares eligible for sale or subject to rights requiring us to register them for sale could cause the market price of the ADSs to drop significantly, even if our business is performing well.

We have filed registration statements on Form S-8 under the Securities Act to register all ordinary shares issued or issuable under our equity plans. Such Form S-8 registration statements have become, and any other registration statements on Form S-8 we file in the future will become, effective upon filing, upon which shares registered under such registration statements become available for sale in the open market.

Additionally, certain sales of ADSs or our ordinary shares that we have made have included, and we may in the future make sales including, holding period restrictions or registration rights. Sales of ADSs or our ordinary shares as restrictions end or pursuant to registration rights may make it more difficult for us to finance our operations through the sale of equity securities in the future at a time and at a price that we deem appropriate. These sales also could cause the trading price of the ADSs to fall and make it more difficult to sell the ADSs on favorable terms.

If we are a “passive foreign investment company” for U.S. federal income tax purposes, there may be adverse U.S. federal income tax consequences to U.S. investors.

Based on our income and assets, we believe that we should be treated as a PFIC for the preceding taxable year. However, the determination of our PFIC status is made annually based on the factual tests described below. Consequently, while we may be a PFIC in future years, we cannot estimate with certainty at this stage whether or not we are likely to be treated as a PFIC in the current taxable year or any future taxable years. Generally, if, for any taxable year, at least 75 percent of our gross income is “passive income” or at least 50 percent of our gross assets during the taxable year (based on the average of the fair market values of the assets determined at the end of each quarterly period) are assets that produce or are held for the production of passive income, we will be characterized as a PFIC for U.S. federal income tax purposes. Passive income for this purpose generally includes, among other things, dividends, interest, rents, royalties, gains from commodities and securities transactions, and gains from assets that produce passive income. However, rents and royalties received from unrelated parties in connection with the active conduct of a trade or business should not be considered

passive income for purposes of the PFIC test. For example, if we were to be characterized as a PFIC for U.S. federal income tax purposes in any taxable year during which a U.S. Holder (as defined in “Taxation —Material United States federal income tax considerations”) holds ordinary shares or ADSs, such U.S. Holder could be subject to additional taxes and interest charges upon certain distributions by us and any gain recognized on a sale, exchange or other disposition of our shares, whether or not we continue to be characterized as a PFIC. Certain adverse consequences of PFIC status can be mitigated if a U.S. Holder makes a “mark to market” election or a “Qualified Electing Fund” (QEF) election. We intend to provide U.S. holders with the information necessary to make and maintain a QEF election for any taxable year in which we are treated as a PFIC. See “Taxation —Material United States federal income tax considerations —Passive foreign investment company considerations.”

Whether we are a PFIC for any taxable year will depend on the composition of our income and the composition and value of our assets from time to time. Each U.S. Holder is strongly urged to consult its tax advisor regarding these issues and any available elections to mitigate such tax consequences.

Item 4. Information on the Company

A. History and Development of the Company

We are committed to improving the health of people worldwide with our fundamental research and development of immunotherapies. Scientific rigor, innovation and passion are our driving forces. BioNTech was founded by scientists and physicians to translate science into survival by combining fundamental research and operational excellence.

We were founded and incorporated on June 2, 2008 as Petersberg 91, V AG, a German stock corporation (*Aktiengesellschaft*). We changed our name to BioNTech AG on December 11, 2008. On March 8, 2019, we converted to a European stock corporation (*Societas Europaea*, or *SE*) under the laws of Germany and the European Union called BioNTech SE. We completed our initial public offering in October 2019. ADSs representing our ordinary shares are currently listed on the Nasdaq Global Select Market under the symbol “BNTX”.

Our principal executive offices are located at An der Goldgrube 12, D-55131 Mainz, Germany. Our telephone number is +49 6131-9084-0. Our website address is www.biontech.com. The information contained on, or that can be accessed through, our website is not part of this document. Our agent for service of solely for the purpose of notices and communications from the Securities and Exchange Commission in the United States is c/o BioNTech US Inc., 40 Erie Street, Suite 110, Cambridge, Massachusetts 02139, +1 (617) 337-4701.

B. Business Overview

I. Overview

We are a global next-generation immunotherapy company pioneering novel medicines against cancer, infectious diseases and other serious diseases. Since our founding in 2008, we have focused on harnessing the power of the immune system to address human diseases with unmet medical needs and major global health burdens. Our fully integrated model combines decades of research in immunology with a multi-technology innovation engine, GMP manufacturing, translational drug discovery, clinical development, commercial capabilities, computational medicine, data science and artificial intelligence (AI) and machine learning (ML) capabilities to discover, develop and commercialize our marketed products and product candidates.

We have built a broad toolkit across multiple technology platforms, including a diverse range of potentially first-in-class therapeutic approaches. This includes investigational messenger ribonucleic acid, or mRNA vaccines, protein-based therapeutics (including targeted antibodies such as monoclonal, bispecific and antibody-drug conjugates, or ADCs), cell therapies and small molecules.

We expect each platform to yield a pipeline of product candidates for further development. Our multi-technology combination of platforms and product candidates positions us as pioneers in the field of individualized, patient-centric therapeutic approaches in oncology and infectious diseases. We aim to expand this status into other disease areas in the future.

In oncology, we endeavor to address the continuum of cancer patients. The root causes of cancer treatment failure are cancer heterogeneity and interindividual variability. Driven by random sequential mutations, every patient's cancer is different and within one patient's tumor, every cell is different. Addressing these two challenges is the core of our strategy. To augment anti-tumor activity and to counteract resistance mechanisms we seek to combine compounds with non-overlapping, synergistic mechanisms of action.

In infectious disease, our product strategy is rooted in global social responsibility and our goal of contributing to equitable access to medicine.

Our approach has generated a robust and diversified product pipeline across a range of technologies in oncology and infectious disease, and has led to the approval of our first marketed product, *Comirnaty*.

II. The BioNTech Approach

Our key objectives are to build a sustainable respiratory infectious disease vaccine business based on the BioNTech-Pfizer *Comirnaty* franchise and to develop an innovative precision medicine pipeline targeting multiple product approvals in the coming years. We are uniquely positioned to pursue our objectives by leveraging our technology agnostic approach rooted in decades of research in immunology coupled with expertise in emerging mRNA technologies. Our vision is to establish a multi-product company based on our pioneering technologies and science to contribute to improving the health of people worldwide.

Oncology Pipeline Strategy

Cancer is one of the biggest medical challenges of humankind. Genetic and phenotypic heterogeneity, the tumor microenvironment and immune diversity make cancer a complex and heterogeneous disease. Our long-term oncology vision is to expand the number of available treatment options for cancer patients. We aim to address the full continuum of cancer treatment by developing novel therapies to best serve the needs of cancer patients from adjuvant to late-stage settings.

Since our founding, we have been a multi-technology company. We believe that by combining complementary treatment modalities, we can leverage the potential of each technology to provide precise and personalized treatments to patients. Such treatments, if approved, could both increase the likelihood of therapeutic success and reduce the risk of therapeutic resistance. By building a diverse toolkit and clinical portfolio with synergistic mechanisms of action we aim to exploit the potential of our technologies:

- **Immunomodulators.** We are building a modality agnostic toolkit to focus on crucial immuno-oncology pathways. We target different but complementary players in the complex cancer immunity cycle to promote a thorough and durable antitumor effect. We use our in-house capabilities and collaborate with Genmab A/S, or Genmab, OncoC4, Inc., or OncoC4, and Biotheus Inc., or Biotheus, to develop next-generation immunomodulators that are designed to modulate the patient's immune response to cancer.
- **Targeted Therapies.** We aim to develop potent and precise therapies that could reduce tumor burden across the entire disease continuum, including late lines. In 2023, we expanded our targeted therapy portfolio by adding several next-generation ADCs to our clinical pipeline through collaborations with Duality Biologics (Suzhou) Co. Ltd., or DualityBio, and MediLink Therapeutics (Suzhou) Co., Ltd., or MediLink Therapeutics. ADCs will transform cancer care. We believe they have the potential to supplement or replace chemotherapy in the future. We believe that a differentiated ADC linker technology could improve efficacy and safety compared to currently approved ADCs, and novel mechanisms of action may be able to improve tumor specific activation. We are also developing a range of cell therapies against solid tumors, including chimeric antigen receptor, or CAR-T cell therapies, neoantigen-based T-cell therapies and T-cell receptor, or TCR therapies in which the patient's T cells are modified or primed to target cancer-specific antigens.
- **mRNA Vaccines and mRNA Therapeutics.** We are developing a portfolio of mRNA-based therapeutic candidates to treat cancer: cancer vaccine candidates, including FixVac (fully-owned) and iNeST (in collaboration with Genentech, Inc., a member of the Roche group, or Genentech), and mRNA-encoded cytokines and antibodies. We believe that mRNA cancer vaccine candidates, if successful, could have the potential to eliminate polyclonal residual disease by targeting multiple antigens at once for potential long-term impact.

We expect to continue building our oncology pipeline in 2024 in anticipation of potential commercial oncology launches as soon as 2026, if approved. We aim to have ten indication approvals by 2030.

Infectious Disease Pipeline Strategy

Infectious diseases remain among the leading causes of death and disability worldwide: in 2019, an estimated 13.7 million lives were lost to infectious diseases globally. Low- and middle-income countries continue to bear much of the burden of communicable diseases, which include tuberculosis, human immunodeficiency virus, or HIV, malaria, neglected tropical diseases and hepatitis B. Climate change, rising population numbers and global travel may all contribute to an increased risk of global infectious disease outbreaks.

Our goal is to advance and expand our infectious disease programs by developing vaccines and therapeutics for infectious diseases caused by respiratory viruses, latent viruses, bacteria and parasites. We believe our scientific approach and our mRNA technology have the potential to significantly contribute to the fight against global health threats caused by infectious diseases. We have pursued both strategic partnerships and corporate collaborations to partially fund our infectious disease global health programs. Our infectious disease programs aim to contribute to equitable access to effective and well tolerated vaccines for high medical need indications.

We plan to build a sustainable respiratory vaccine business, leveraging our COVID-19 vaccine franchise for potential combination vaccines. We expect seasonal COVID-19 vaccination to continue, driven by the continuous evolution of the virus. We are also evaluating combination vaccine candidates addressing additional respiratory diseases in collaboration with Pfizer Inc., or Pfizer.

We and our partners are committed to developing product candidates against latent viruses, including herpes-simplex virus (HSV) and varicella-zoster virus (shingles). Latent viruses remain in the body after an infection and can lead to lifelong medical complications.

In addition, we have ongoing trials evaluating mRNA vaccine candidates against diseases caused by bacteria (tuberculosis) and parasites (malaria).

Longer term, we see potential applications for our technologies beyond oncology and infectious disease, including autoimmune diseases, inflammatory diseases, cardiovascular diseases, neurodegenerative diseases, and regenerative medicines.

III. Execution in 2023

In 2023, we executed across our four key strategic pillars to strengthen our technology platforms, digital capabilities and infrastructure, through strategic investments, acquisitions, licensing agreements and public-private partnerships impacting patients, shareholders and other stakeholders.

1. Leadership in COVID-19 Vaccine Development

We continued to build our COVID-19 vaccine franchise and maintained market leadership in multiple key geographies. In 2023, we and Pfizer distributed over 460 million total *Comirnaty* doses, of which over 190 million doses were our Omicron XBB.1.5-adapted monovalent COVID-19 vaccine. We and Pfizer introduced single-dose vials and never-frozen syringes in the United States.

2. Healthcare and Social Responsibility

We advanced our goal of contributing to equitable access to medicine around the globe, with over 30% of *Comirnaty* doses delivered to low- and middle-income countries in 2023 in line with demand. We continue to work with non-governmental organizations (NGOs), institutes and governments to plan for equitable access to novel medicines, especially in low and middle-income countries and regions.

Our global health goal is to advance and expand our infectious diseases programs and pipeline while contributing to equitable access to mRNA medicines. To further advance this vision, we established our Global Health Office (GHO) in 2023. The GHO provides a public health perspective supporting end-to-end development of innovative medicines that address major unmet public health needs, particularly those affecting populations in low- and middle-income countries and those with an inequity or pandemic preparedness dimension. The GHO leads on building clinical development and manufacturing capacity to support our goals; this includes the “AFRIKA KOMMT” program, where we hosted our first batch of fellows for internships in Germany in 2023. The GHO works closely with a large ecosystem of partners including the WHO, African Union, Africa CDC, local authorities, study centers, and organizations like CEPI and Gavi, the Vaccine Alliance.

We are progressing the development of mRNA vaccine candidates for infectious diseases with high medical need, including vaccine candidates against tuberculosis, malaria, and HIV, as well as against infectious diseases with pandemic potential, such as mpox. In December 2023, we reached an important milestone towards the establishment of mRNA vaccine manufacturing capacities in Africa with the inauguration of our facility in Kigali, Rwanda.

3. Innovative and Diversified Pipeline

We continued to develop our innovative oncology and infectious disease pipeline. Today, our pipeline consists of over 20 programs in oncology and seven programs in infectious disease being evaluated in over 40 clinical trials, including eight Phase 2 and two Phase 3 clinical trials in oncology. In 2023, we and our partners reported data across our portfolio at multiple medical meetings and published manuscripts in peer reviewed journals.

In oncology, we started seven clinical trials and in-licensed six clinical assets throughout the year. Most importantly, we brought several assets into mid- and late-stage development, namely Phase 2 and Phase 3 clinical trials, across a range of technologies, in particular ADCs and mRNA vaccines.

We expanded our technology base to include ADCs by initiating new collaborations with DualityBio and MediLink Therapeutics. We believe ADCs have the potential to supplement or replace highly toxic chemotherapy regimens as a new combination backbone of cancer treatment. Our growing ADC pipeline includes ADCs directed against four distinct targets and is of interest for a broad range of cancer types. Our collaborations with OncoC4 and Biotheus complement our toolkit of technologies with next-generation immuno-oncology antibodies that offer unique mechanisms of action and have augmented our oncology pipeline with mid- to -late-stage clinical programs.

In infectious diseases, we started three first-in-human Phase 1 clinical trials leveraging our proprietary mRNA prophylactic vaccine technology, including candidates being evaluated against shingles, tuberculosis, and mpox.

Over the next year, we aim to advance additional product candidates to late-stage development, and we expect to have ten or more potentially registrational trials running by the end of 2024. The Company expects to continue building its pipeline towards its planned first oncology launch in 2026. BioNTech aims to have ten indication approvals by 2030.

4. Innovation at Scale

We are building and scaling biotech innovation with the aim of becoming a patient-centric, AI-driven, multi-product company. In 2023, we attracted top talent, including clinical and regulatory experts, to advance the development of our pipeline. We expanded our team to roughly 6,300 employees globally by welcoming more than 1,600 new hires. Our diverse workforce represents more than 80 nations, and we have subsidiaries in countries across five continents.

In 2023, we expanded our organization in Asia, Africa, North America, Australia and Europe. We increased our overall research and development and production capabilities, including completing construction of our first proprietary plasmid DNA manufacturing facility in Marburg, Germany. Furthermore, we established a corporate office in Shanghai, China.

In 2023, we entered into multiple complementary agreements and collaborations, including:

- The completion of the acquisition of our long-time strategic collaboration partner, InstaDeep Ltd, or InstaDeep, which enables us to leverage AI and ML technologies across our therapeutic platforms and operations. With our acquisition of InstaDeep, we have added industry-leading AI and ML capabilities and approximately 290 highly skilled professionals to our organization. InstaDeep operates as a London-based subsidiary.
- A strategic collaboration with the Government of the United Kingdom, or the UK, to provide up to 10,000 patients with personalized mRNA cancer immunotherapies by 2030, either in clinical trials or as authorized treatments. We plan to invest in a research and development hub in Cambridge, UK, with an expected capacity of more than 70 highly skilled scientists.
- A multi-year agreement with Australia's State of Victoria to set up and operate clinical-scale mRNA vaccine manufacturing through our *BioNTainer* units and establish an mRNA Innovation Center in Melbourne.

Post year-end, in February 2024, in line with our goal of scaling up innovation, we and Autolus Therapeutics plc, or Autolus, announced a strategic collaboration aimed at advancing both companies' autologous CAR-T programs towards commercialization, pending regulatory authorizations. As part of the strategic collaboration, we have the option to access Autolus' commercial and clinical site network, and manufacturing capacities in the UK and commercial supply infrastructure in a cost-efficient set-up allowing for the accelerated development of our product candidate, BNT211.

In 2023, we strengthened our balance sheet through strong financial performance, ending the year with approximately €17.7 billion in total cash, cash equivalents and security investments. With a strong financial position, leading COVID-19 vaccine franchise, and innovative oncology and infectious disease pipeline, we believe are well positioned to continue executing our vision of pioneering novel medicines against cancer, infectious diseases and other serious diseases.

IV. Marketed Products: *Comirnaty*, our COVID-19 Vaccine Program (BNT162)

Our commercial product, *Comirnaty*, was the first-ever approved mRNA-based product, and, to our knowledge, represents the fastest ever developed prophylactic vaccine from viral sampling to approval. As of December 2023, our COVID-19 vaccine products have been authorized or approved for emergency or temporary use or granted marketing authorization in more than 180 countries and regions worldwide. Our efforts have resulted in more than 4.8 billion doses shipped globally.

Under our collaboration with Pfizer, we are the Marketing Authorization Holder in the United States, the European Union, or EU, the UK, Canada and other countries. Additionally, we are the holder of emergency use authorizations, or EUAs, or equivalents in the United States (jointly with Pfizer) and other countries for the COVID-19 vaccine program. Pfizer has marketing and distribution rights worldwide apart from Greater China, Germany, and Türkiye. We have the marketing and distribution rights to *Comirnaty* in Germany and Türkiye.

Under our collaboration with Fosun Pharmaceutical Industrial Development, Co., Ltd, or Fosun Pharma, Fosun Pharma has marketing and distribution rights in Mainland China, Hong Kong Special Administrative Region, or SAR, Macau SAR and Taiwan.

1. Commercial Update

In 2023, we and Pfizer continued our global COVID-19 vaccine leadership with our Omicron XBB.1.5-adapted monovalent COVID-19 vaccine directed against the Omicron XBB.1.5 SARS-CoV-2 variant. Since declaration of the pandemic, we have developed and commercialized four COVID-19 vaccine products: the original COVID-19 vaccine, two Original/Omicron-adapted bivalent vaccines (Original/BA.1- and Original/Omicron BA.4-5-adapted bivalent vaccines) and the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine. Each is referred to as *Comirnaty*. Between their introduction in December 2020 and March 2023, COVID-19 vaccines are estimated to have reduced deaths due to the pandemic by at least 57%, saving more than 1.4 million lives in the World Health Organization, or WHO, European Region. Most of those saved were aged 60 or older, the group at highest risk of severe illness and death from the SARS-CoV-2 virus.

As part of our and Pfizer's two-billion-doses pledge to support equitable access to medicines, we and Pfizer have delivered over 1.8 billion doses of *Comirnaty* to low- and middle-income countries since the beginning of the pandemic in line with demand.

In September 2023, following regulatory approvals, we and Pfizer began shipping Omicron XBB.1.5-adapted monovalent COVID-19 vaccines in time for autumn and winter booster campaigns.

We believe that we and Pfizer are well positioned for the future as leading COVID-19 vaccine providers. We expect that as the market dynamics evolve across different geographies in 2024, there will be continued demand for vaccine boosting and primary vaccinations of immunologically naïve individuals, especially amongst older and immunocompromised populations. Studies have demonstrated that natural immunity acquired by SARS-CoV-2 infection is variable across individuals and the protection it offers wanes over time. A booster vaccination can restore and enhance infection-acquired immune protection and further reduce the risk of reinfection. The risk of severe COVID-19 disease remains high in vulnerable populations. Vaccination not only reduces the risk of severe COVID-19 but can also mitigate the risk of health impairments related to long-COVID. Given this, and our current understanding of COVID-19's seasonality and its burden on healthcare systems during the autumn/winter season, we anticipate the need for annual adapted vaccines to be a long-term component of COVID-19 vaccination practices.

2. Manufacturing and Distribution

We and Pfizer continue to collaborate with governments and health ministries around the world to efficiently distribute *Comirnaty*. We have developed a global COVID-19 vaccine supply chain and manufacturing network spanning four continents to meet the ongoing global demand of *Comirnaty*.

In 2023, we began transitioning from an advanced purchase agreement framework to commercial market ordering in some geographies.

In May 2023, we and Pfizer announced an agreement with the European Commission, or the EC, to amend the previous COVID-19 Vaccine Purchase Agreement to deliver COVID-19 vaccines to the EU. The amended agreement reflects our and Pfizer's commitment to working collaboratively to help address ongoing public health needs, while respecting the principles of the original agreement. The agreement rephased delivery of doses annually through 2026. In addition, the agreement includes an aggregate volume reduction, providing additional flexibility for EU Member States. The EC will maintain access to future adapted COVID-19 vaccines and the ability to donate doses, in alignment with the original agreement.

In October 2023, we and Pfizer announced an agreement between the Japanese government and Pfizer Japan Co., Ltd. to supply an additional nine million doses of the Omicron XBB.1.5-adapted COVID-19 vaccine for the special vaccination program in Japan which started in autumn 2023. The agreement followed an agreement between the Japanese government and Pfizer in July 2023 to supply 20 million doses and additional supplies as needed, and an agreement announced in September 2023 to provide an additional 10 million doses of the companies' Omicron XBB.1.5-adapted COVID-19 vaccine for the special vaccination program in Japan.

More details on our manufacturing operations and facilities can be found in "VII. Manufacturing."

3. Clinical Development

Omicron XBB.1.5-Adapted Monovalent COVID-19 Vaccine

In August 2023, we and Pfizer initiated a Phase 2/3 study (NCT05997290) to investigate the safety, tolerability and immunogenicity of our Omicron XBB.1.5-adapted monovalent COVID-19 vaccine in healthy people 12 years and older. A manuscript reporting the safety and immunogenicity one month after vaccination with our monovalent Omicron XBB.1.5-adapted COVID-19 vaccine in COVID-19 experienced individuals 12 years of age and older was published in January 2024 (Gayed et al., 2024). These data support a favorable benefit-risk profile of our XBB.1.5-adapted COVID-19 vaccine. In this analysis, the XBB.1.5-adapted vaccine demonstrated a safety and tolerability profile similar to that seen with original and the BA.4/5-adapted and BA.1-adapted COVID-19 vaccines and induced substantial increases in neutralizing antibody responses against Omicron XBB.1.5 (overall geometric mean fold rises [GMFR]: 7.0), EG.5.1 (GMFR: 8.7), and BA.2.86 (GMFR: 4.5). We believe the safety and immunogenicity data support administration of the XBB.1.5-adapted BNT162b2 in vaccine-experienced individuals 12 years of age and older.

Real world data showed high vaccine effectiveness of the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine against current variants of concern, with 63% (95%CI: 33-80%) vaccine effectiveness against hospitalization observed in adults aged 18 years and older approximately 30 days post vaccination in the United States against XBB.1.5, XBB.1.16, EG.5.1, and BA.2.86. Similar real world evidence trends have been reported in EU countries. In Denmark, vaccination was associated with a 75.3% reduced risk of COVID-19 hospitalization nine days post-immunization with a monovalent XBB.1.5 in people over 65 years of age. In the Netherlands, early estimate demonstrated a high vaccine effectiveness against hospitalization (68.3 – 71.4%) and ICU admission (73.3%) in people over 60 years of age in the two months post vaccination with XBB.1.5 vaccine.

In 2023, we and Pfizer announced positive pre-clinical data examining our Omicron XBB.1.5-adapted monovalent COVID-19 vaccine against multiple Omicron XBB-related sublineages, including XBB.1.5, XBB.1.16, BA.2.86, EG.5.1 and XBB.2.3, compared to the Omicron BA.4-5-adapted bivalent vaccine. These data demonstrate that the XBB.1.5-adapted COVID-19 vaccine generates improved neutralizing antibody responses against all Omicron-related sublineages mentioned above.

4. Regulatory Updates

In 2023, our and Pfizer's Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine received label expansions for pediatric vaccinations and conversions from conditional or emergency use approvals or authorizations to full/standard regulatory approvals in many jurisdictions worldwide.

Our and Pfizer's Omicron XBB.1.5-adapted monovalent COVID-19 vaccine received multiple regulatory approvals, including approvals, authorization: for emergency or temporary use or marketing authorizations in more than 40 countries and regions in 2023.

Original/Omicron BA.4-5-Adapted Bivalent COVID-19 Vaccine

In 2023, we and Pfizer received the following approvals for our Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine:

- March 2023: U.S. Food and Drug Administration, or U.S. FDA approved an EUA for a single booster dose of our Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine for children six months through four years of age at least two months after completion of primary vaccination with three doses of the original COVID-19 vaccine.
- April 2023: U.S. FDA updated this EUA to simplify the vaccination schedule for most individuals. This action included authorizing our original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine to be used for all doses administered to individuals six months of age and older.

Omicron XBB.1.5-Adapted Monovalent COVID-19 Vaccine

In 2023, we and Pfizer received the following approvals for our Omicron XBB.1.5-adapted monovalent COVID-19 vaccine:

- August 2023: the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA recommended marketing authorization for our and Pfizer's Omicron XBB.1.5-adapted

monovalent COVID-19 vaccine administered as a single dose for individuals five years of age and older, regardless of prior COVID-19 vaccination history. The CHMP also recommended the updated vaccine for children six months through four years of age as part or all of the primary three-dose vaccination series, depending on how many prior doses received, or as a single dose for those with a history of completion of a COVID-19 primary vaccination course or prior SARS-CoV-2 infection. Positive EC Decisions followed CHMP recommendations the day after.

- September 2023: U.S. FDA approved a supplemental Biologics License Application (BLA) for the monovalent XBB.1.5-adapted vaccine recommended for use in the 2023-2024 autumn and winter season for individuals 12 years of age and older, and granted an EUA for children six months through 11 years of age.
- Other national healthcare regulatory bodies, including in the UK, Japan, Canada, Australia and South Korea, have also approved our and Pfizer’s monovalent XBB.1.5-adapted vaccine.

V. Pipeline of Product Candidates

We are advancing a broad portfolio of product candidates derived from our four drug classes and multiple platforms, and are focused on immunotherapies for the potential treatment of cancer and mRNA vaccines to potentially prevent or treat infectious diseases.

Oncology Pipeline

Oncology									
Drug class	Platform	Product candidate	Indication (target)	Phase 1	Phase 1/2	Phase 2	Phase 3	BioNTech rights ¹	Collaborator/ Partner
mRNA	FixVac	BNT111	Advanced, R/R melanoma	█	█	█		Fully owned ²	
		BNT113	Metastatic/ R/R HPV16+ head and neck cancer	█	█	█			
		BNT116	1L metastatic NSCLC	█	█	█			
mRNA	iNeST	BNT122 (autogene cevumeran)	1L advanced melanoma	█	█	█		Collaboration	Genentech ³
			Adjuvant colorectal cancer	█	█	█			
			Adjuvant pancreatic ductal adenocarcinoma	█	█	█			
			Multiple solid tumors	█	█	█			
mRNA	RiboMabs	BNT142	Multiple solid tumors (CD3×CLDN6)	█	█	█		Fully owned	
	RiboCytokines	BNT151	Multiple solid tumors (IL-2 variant)	█	█	█			
		BNT152 + BNT153	Multiple solid tumors (IL-7, IL-2)	█	█	█			
Cell therapies	CAR T cells + CARVac	BNT211	Multiple solid tumors (CLDN6)	█	█	█		Fully owned	
		BNT221	Refractory metastatic melanoma	█	█	█			
Cell therapies	Neoantigen-based T cells	BNT311 / GEN1046 (acaunimab)	aPD(L)1-R/R metastatic NSCLC (PD-L1×4-1BB)	█	█	█		Collaboration	Genmab
		BNT312 / GEN1042	Multiple solid tumors (PD-L1×4-1BB)	█	█	█			
		BNT313 / GEN1053	Multiple solid tumors (CD40×4-1BB) ⁴	█	█	█			
		BNT314 / GEN1059	Multiple solid tumors (CD27)	█	█	█			
		BNT322 / GEN1056	Multiple solid tumors (EPCAM×4-1BB)	█	█	█			
		BNT322 / GEN1056	Multiple solid tumors	█	█	█			
Protein-based therapeutics	Targeted cancer antibodies	BNT316 / ONC-392 (gotisobart)	aPD(L)1-R/R metastatic NSCLC (CTLA-4)	█	█	█		Collaboration	OncoC4
			Platinum-resistant ovarian cancer (CTLA-4)	█	█	█			
			Metastatic castration-resistant prostate cancer (CTLA-4)	█	█	█			
Protein-based therapeutics	Antibody-drug conjugates	BNT321	Pancreatic cancer (sLea)	█	█	█		Fully owned	
		BNT323 / DB-1303	Multiple solid tumors (HER2)	█	█	█			
		BNT324 / DB-1311	2L+, HR+/HER2-low metastatic breast cancer (HER2)	█	█	█			
		BNT325 / DB-1305	Multiple solid tumors (B7H3)	█	█	█			
Protein-based therapeutics	Antibody-drug conjugates	BNT326/YL202	Multiple solid tumors (TROP2)	█	█	█		Collaboration	MediLink Therapeutics
		BNT411	Multiple solid tumors (HER3)	█	█	█			
SMI ⁵	Toil-like receptor binding	BNT411	Multiple solid tumors (TLR7)	█	█	█		Fully owned	

Infectious Disease Pipeline

Infectious Diseases

Drug class	Product candidate	Indication	Phase 1	Phase 1/2	Phase 2	Phase 3	Commercial	BioNTech rights	Collaborator/ Partner	
mRNA	COMIRNATY (BNT162b2)	COVID-19	[Progress bar]						Collaboration	Pfizer Fosun Pharma
	COMIRNATY-BNT162b4 (T-cell enhancing)		[Progress bar]							
	BNT162b5/6/7 (Stabilized spike antigen)		[Progress bar]							
	COMIRNATY-BNT161 ⁶	COVID-19 – influenza combination	[Progress bar]						Collaboration	Pfizer
	BNT161	Influenza	[Progress bar]						Collaboration ⁷	Pfizer
	BNT163	HSV	[Progress bar]						Collaboration	University of Pennsylvania
	BNT164	Tuberculosis ⁸	[Progress bar]						Fully owned	Funded by Bill & Melinda Gates Foundation
	BNT165	Malaria ⁹	[Progress bar]						Fully owned	
	BNT166	Mpox	[Progress bar]						Fully owned	Funded by CEPI ¹⁰
	BNT167	Shingles	[Progress bar]						Collaboration	Pfizer

¹ For further details about BioNTech's rights see quarterly reports under <https://investors.biontech.de/financials-filings/quarterly-reports>.
² FixVac platform is fully owned by BioNTech. The BNT111 and BNT110 Phase 2 trials are jointly conducted with Regeneron as part of a cost-sharing strategic collaboration.
³ A member of the Roche group.
⁴ Two Phase 1/2 clinical trials in patients with solid tumors are ongoing in combination with IC1+/- chemotherapy.
⁵ Small molecule immunomodulators.
⁶ The COVID-19-influenza combination is a Phase 3 trial in partnership with Pfizer. Further development is subject to entering into a definitive agreement.
⁷ Out-licensed to Pfizer.
⁸ Two Phase 1 clinical trials are ongoing (NCT05527038, Germany and NCT05547454, Republic of South Africa).
⁹ A Phase 1 clinical trial (NCT05551641) and a Phase 1/2 clinical trial (NCT05555441) are ongoing.
¹⁰ Coalition for Epidemic Preparedness Innovations (CEPI).

A. Oncology Programs

1. mRNA Product Class in Oncology

a) FixVac

FixVac is our wholly owned, systemic, off-the-shelf mRNA-based cancer immunotherapy approach, from which we are developing several first-in-human and potential first-in-class product candidates. *FixVac* product candidates contain our non-nucleoside optimized uridine-RNA delivered in our proprietary RNA-LPX formulation for intravenous administration. Proprietary RNA-LPX is designed to deliver RNA to dendritic cells, or DCs, and protects RNA from degradation by RNase and is designed for RNA delivery into antigen-presenting cells in lymphoid organs. *FixVac* candidates are designed to target shared antigens that have been identified to be frequently expressed across patients with a specific cancer type. These product candidates are designed to trigger both innate and adaptive immune responses.

i. BNT111 for the Treatment of Advanced Melanoma

BNT111 is designed to elicit an immune response to four antigens (NY-ESO-1, MAGE-A3, tyrosinase, TPTE) that have each been found to be associated with cutaneous melanoma.

Ongoing Phase 2 Trial

A global, randomized three-arm Phase 2 clinical trial (NCT04526899) is being conducted in collaboration with Regeneron Pharmaceuticals Inc., or Regeneron, and is evaluating BNT111 in combination with cemiplimab (Regeneron's Libtayo) versus both agents as monotherapy in 184 patients with anti-PD-1-/anti-PD-L1 refractory/relapsed, unresectable Stage III or IV melanoma. The primary endpoint is objective response rate (ORR). Secondary endpoints include duration of response (DOR), disease control rate (DCR), time to response (TTR), progression-free survival (PFS), overall survival (OS) and safety. The trial achieved full enrollment in September 2023.

Phase 1 Trial (LIPO-MERIT)

A multi-center, open-label, first-in-human, Phase 1 dose escalation clinical trial (NCT02410733) evaluating the safety and tolerability of BNT111 in patients with advanced melanoma has been completed. This was the first clinical trial worldwide in which an mRNA-based cancer immunotherapy was administered intravenously for systemic treatment.

- The trial started in 2015, enrollment was completed in 2020 with 115 patients and the last patient visit under the follow-up period took place in June 2023. Final biomarker and clinical data of the trial are being gathered and evaluated and will be compiled in a clinical study report.

ii. BNT112 for the Treatment of Prostate Cancer

BNT112 is designed to elicit an immune response to five antigens expressed *irde novo* and metastatic prostate cancer, including prostate-specific antigen, or PSA, a transmembrane protein that is expressed by virtually all prostate cancers, prostatic acid phosphatase, or PAP, and three additional tumor-associated antigens.

Phase 1/2a Clinical Trial (PRO-MERIT)

PRO-MERIT is a first-in-human Phase 1/2a, open-label dose titration and expansion clinical trial (NCT04382898) to evaluate the safety, immunogenicity and preliminary efficacy of BNT112 monotherapy and in combination with cemiplimab in patients with metastatic castration resistant prostate cancer, or mCRPC and high-risk localized prostate cancer (LPC) who are eligible for treatment with androgen deprivation therapy (ADT) followed by radical prostatectomy. The trial has been discontinued and the follow-up period ended in January 2024. Final data of the trial are being gathered and evaluated and will be compiled in a clinical study report.

iii. BNT113 for the Treatment of Human Papilloma Virus 16-positive, or HPV16+, Head and Neck Cancer, or HNSCC

BNT113 encodes two HPV-16-related oncoproteins exclusively expressed in pre-malignant and malignant tissue. HPV-associated cancers are increasing, with HPV16+ HNSCC typically occurring in younger populations. Most patients with HPV16+ HNSCC are diagnosed at more advanced clinical stages. We see a significant opportunity to improve the treatment landscape with BNT113 given that it has the potential to augment clinical responses in patients being treated with checkpoint inhibitors.

Ongoing BNT113 Phase 2 Trial (AHEAD-MERIT)

A global randomized Phase 2 clinical trial (NCT04534205) evaluating BNT113 in combination with pembrolizumab (Merck & Co., Inc.'s Keytruda) versus pembrolizumab monotherapy as a first-line treatment in patients with unresectable recurrent or metastatic HPV16+ HNSCC expressing PD-L1 is ongoing. Part A is a non-randomized run-in portion designed to demonstrate the safety of the combination of BNT113 and pembrolizumab. Part B is the randomized portion of the trial designed to generate efficacy and safety data. The trial plans to enroll a total of 267 patients.

Phase 1/2 Trial (Investigator-Initiated and Sponsored)

BNT113 was investigated by the University Hospital Southampton National Health Service (NHS) Foundation Trust in an investigator-sponsored open-label, Phase 1/2 dose escalation basket clinical trial with two different arms in 29 patients with HPV16+ head and neck and other cancers in the post-adjuvant and metastatic setting. The trial has been terminated and the patient follow-up period ended in July 2023.

iv. BNT114 for the Triple Negative Breast Cancer, or TNBC

A multi-center, open-label, three-arm Phase 1 clinical trial (NCT02316457) to evaluate BNT114 as monotherapy and in combination with our individualized neoantigen specific immunotherapy in TNBC patients who had previously received the standard of care therapy (i.e., surgery, chemotherapy and/or radiotherapy) had its last patient last visit in May 2023. The trial results of the main study phase were summarized in a clinical trial report, or CTR, in 2021. The data generated within the three-year long-term follow-up period has been described in an addendum to the CTR.

v. BNT115 for the Treatment of Ovarian Cancer

Phase 1 Trial (Investigator-Initiated and Sponsored)

BNT115 was studied in an investigator-initiated and -sponsored first-in-human, open-label Phase 1 dose escalation clinical trial in ovarian cancer patients eligible for standard-of-care treatment with (neo-) adjuvant chemotherapy. Although the original recruitment period was extended, the target number of evaluable patients, defined in the study protocol was not reached and recruitment for the trial was stopped. Recruitment of 10 patients was concluded in June 2022, and eight were ultimately dosed. The follow-up phase for the enrolled patients was completed in June 2023. The clinical data of the trial will be evaluated by the University Medical Center Groningen, Netherlands and recorded accordingly. No follow-up studies are planned with BNT115.

vi. BNT116 for the Treatment of Non-small Cell Lung Cancer, or NSCLC

BNT116 is being evaluated in two clinical trials as a monotherapy and in combination with other immunotherapies and chemotherapies in patients with advanced or metastasized NSCLC.

Ongoing Phase 2 Trial in NSCLC 1L

A randomized, controlled Phase 2 clinical trial (NCT05557591) is ongoing to evaluate BNT116 in combination with cemiplimab versus cemiplimab alone as first-line treatment of patients with advanced NSCLC whose tumors express PD-L1 in $\geq 50\%$ of their tumor cells. The primary objective of the Phase 2 trial is to assess the safety and tolerability as well as the ORR and tumor burden reduction.

- In October 2023, a Trial-in-Progress poster was presented at the European Society for Medical Oncology (ESMO) Congress.

Ongoing Phase 1 Trial in NSCLC

A Phase 1 clinical trial (NCT05142189) is ongoing to evaluate the safety, tolerability and preliminary efficacy of BNT116 alone and in combination with cemiplimab in patients who have progressed on prior PD-1 inhibitor treatment or are not eligible for chemotherapy, in combination with docetaxel in patients who have received prior PD-1 inhibitor therapy and platinum-based chemotherapy, in combination with cemiplimab in patients with unresectable Stage III NSCLC who have undergone chemoradiotherapy, and in combination with cemiplimab with or without chemotherapy in the neoadjuvant and adjuvant settings in patients with resectable Stage II and III NSCLC.

- In September 2023, two new cohorts were added to the study: a cohort enrolling NSCLC patients to evaluate BNT116 combination with cemiplimab and chemotherapy in the neo- and adjuvant settings; and a cohort to assess the potential of BNT116 plus cemiplimab as consolidation treatment after concurrent chemoradiotherapy.
- First data from the trial were presented at the 2023 Society for Immunotherapy of Cancer (SITC) Annual Meeting. The tolerability profile of BNT116 was similar to other RNA-LPX-based therapeutic vaccines. In heavily pretreated NSCLC patients, early clinical activity was observed with treatment with BNT116 with the addition of cemiplimab from cycle 3 onward.

b) Autogene Cevumeran (BNT122), an Individualized Neoantigen Specific Immunotherapy, or iNeST

Autogene cevumeran is an individualized cancer immunotherapy product candidate based on specific neoantigens that are present on a patient's tumor. Similar to our *FixVac* programs, our *iNeST* approach is also based on a pharmacologically optimized-backbone equipped uridine mRNA, or uRNA, delivered in our proprietary RNA-LPX formulation. Proprietary RNA-LPX is designed to deliver RNA to DCs and protects RNA from degradation by RNase and is designed for RNA delivery into antigen-presenting cells in lymphoid organs. Each patient is treated with a vaccine informed by the mutation profile of their personal cancer and manufactured on-demand. The RNA encodes a unique composition of the patient's own tumor mutations and results in generation of neoantigen specific CD4+ and CD8+ T-cell responses. Each autogene cevumeran dose includes up to 20 different neoantigens selected on a patient-by-patient basis (up to 10 neoantigens on 1 RNA). We believe this modality may be well-suited for use in the adjuvant setting. *iNeST* is partnered with Genentech as part of a 50:50 collaboration in which development costs and future profits are shared.

Ongoing Phase 2 Trial in Adjuvant Colorectal Cancer

A randomized, multi-site, open-label Phase 2 clinical trial (NCT04486378) evaluating autogene cevumeran as an adjuvant treatment of circulating tumor DNA (ctDNA) positive, surgically resected Stage II (high risk)/Stage III colorectal cancer is ongoing. The trial is expected to enroll about 200 patients to evaluate the efficacy of autogene cevumeran compared to watchful waiting after surgery and chemotherapy, the current standard of care for these high-risk patients. The primary endpoint for the study is disease-free survival, or DFS. Secondary objectives include OS and safety. The trial is currently enrolling in the United States, Germany, Spain, Belgium, Sweden and the UK.

Ongoing Phase 2 Trial in Pancreatic Ductal Adenocarcinoma, or PDAC

In October 2023, the first patient was dosed in the randomized Phase 2 clinical trial (NCT05968326) evaluating the safety and efficacy of autogene cevumeran in combination with atezolizumab (Genentech's Tecentriq) followed by standard-of-care chemotherapy (mFOLFIRINOX) in patients with resected PDAC compared to chemotherapy alone. The Phase 2 study is expected to enroll 260 patients with resected PDAC who have not received prior systemic anti-cancer treatment and showed no evidence of disease after surgery. The primary endpoint is DFS. Secondary endpoints include OS and safety. The trial has been initiated in the United States and enrollment is planned in approximately 10 countries in total.

- In May 2023, results from the investigator-initiated Phase 1 trial were published in the peer-reviewed journal *Nature* (Rojas, L.A et al. 2023). The paper reported preliminary evidence that adjuvant autogene cevumeran in combination with atezolizumab and mFOLFIRINOX induces substantial T-cell response in patients with surgically resected PDAC that correlates with delayed recurrence.

Ongoing Phase 2 Trial in First-line Melanoma with Pembrolizumab

A randomized Phase 2 clinical trial (NCT03815058) evaluating the efficacy and safety of autogene cevumeran in combination with pembrolizumab versus pembrolizumab alone as first line in patients with previously untreated advanced melanoma is fully enrolled and follow-up is ongoing. The primary endpoint is PFS and is events-based. Secondary endpoints include ORR, OS, DOR and safety.

Ongoing Phase 1a/1b Clinical Trial

An open-label Phase 1a monotherapy/1b in combination with atezolizumab clinical trial (NCT03289962) of autogene cevumeran in patients with locally advanced or metastatic solid tumors, including patients with melanoma, NSCLC, bladder cancer, colorectal cancer, TNBC, renal cancer, head and neck cancer and sarcomas as well as other solid tumors is fully enrolled and follow-up is ongoing.

c) mRNA Intratumoral Immunotherapy

i. BNT131/SAR441000 for the Treatment of Solid Tumors

BNT131/SAR441000 comprised four mRNAs encoding the cytokines IL-12sc, IL-15sushi, IFN- α and GM-CSF, which we had identified as mediators of tumor regression across different murine tumor models. The Collaboration and License Agreement with Sanofi to develop BNT131/SAR441000 was terminated effective December 30, 2023.

Phase 1 Clinical Trial

We and Sanofi are running a first-in-human, multi-center, open-label, Phase 1, dose escalation and expansion clinical trial (NCT03871348) to evaluate the safety, pharmacokinetics, pharmacodynamics and anti-tumor activity of BNT131/

SAR441000 administered intratumorally as monotherapy and in combination with cemiplimab. In this trial, 77 patients with certain advanced solid tumors were enrolled. The trial has stopped recruitment; treatment of patients and follow-up are ongoing.

- In April 2023, preliminary data from the dose escalation and expansion study trial were presented at the 2023 American Association for Cancer Research (AACR) Annual Meeting. Anti-tumor activity across multiple dose levels was observed with treatment with BNT131/SAR441000 and was primarily limited to loco-regional disease setting. No significant overall distant non-injected lesion response was seen.
- Based on interim analysis results, we and Sanofi have jointly decided to discontinue the development of the mRNA coding for cytokines, BNT131/SAR441000.

d) *RiboMabs*

Our *RiboMab* product candidates, BNT141 and BNT142, are mRNAs that encode cancer cell targeting antibodies. These product candidates leverage our proprietary optimized mRNA technology combining nucleoside modifications to minimize immunogenicity with our improved mRNA backbone designs with the aim of maximizing protein expression. *RiboMab* product candidates are formulated using liver-targeting lipid nanoparticles, or LNPs for intravenous delivery.

i. *BNT141 for the Treatment of Solid Tumors*

In January 2022, we dosed the first patient in an open-label, multi-site, Phase 1/2 dose escalation, safety, and pharmacokinetic clinical trial of BNT141 followed by expansion cohorts in patients with CLDN18.2-positive tumors. The last patient visit was in July 2023. We have decided to discontinue the study based on observations regarding product characteristics, and are working on an optimized formulation of the product candidate for further clinical development.

ii. *BNT142 for the Treatment of Solid Tumors*

BNT142 codes for a T cell engaging bispecific antibody targeting CLDN6, and is being studied in an ongoing, open-label, multi-center Phase 1/2 clinical trial (NCT05262530) in patients with CLDN6-positive advanced solid tumors that have exhausted available standard therapy or are not eligible for such available therapy.

- A trial-in-progress poster was presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. The study is actively recruiting patients in the EU, the UK, the United States and Singapore.

e) *RiboCytokines*

Our *RiboCytokine* product candidates are designed to address the limitations of recombinantly expressed cytokines, including limited serum half-life and production costs. BNT151 and BNT152+153 are nucleoside-modified mRNAs encoding human cytokines fused to human serum albumin. The modified mRNA is formulated with liver-targeting LNPs for intravenous delivery. BNT151 encodes an IL-2 variant, BNT152 encodes IL-7, and BNT153 encodes IL-2.

i. *BNT151 for the Treatment of Solid Tumors*

A first-in-human, open-label, dose escalation, multi-center Phase 1/2 clinical trial (NCT04455620) evaluating BNT151 (encoding an IL-2 variant) safety, pharmacokinetics and pharmacodynamics in patients with multiple solid tumors has been discontinued after the completion of enrollment for the Part 1 monotherapy dose escalation. The follow-up phase for enrolled patients is expected to be completed in 2024, after which the clinical data of the trial will be finally evaluated and reported accordingly.

ii. *BNT152+BNT153 for the Treatment of Solid Tumors*

Ongoing Phase 1 Trial of BNT152+153

An open-label, multi-site, first-in-human Phase 1 clinical trial (NCT04710043) is evaluating the safety, pharmacokinetics, pharmacodynamics, and preliminary anti-tumor activity of a combination of BNT152 and BNT153. The clinical trial is ongoing and enrolling patients with various metastatic or unresectable solid tumors for whom there is no available standard therapy likely to confer clinical benefit or patients who are not candidates for such available therapy. The clinical trial consists of two parts with adaptive design elements. Part 1 consisted of Groups A and B and was completed in May 2023. Group A was a BNT153 monotherapy dose escalation in patients with advanced solid malignancies until the maximum tolerated dose (MTD) or maximum administered dose (MAD) was defined. Group B was a BNT152

monotherapy dose escalation in patients with advanced solid malignancies until the MTD or optimal biological dose (OBD) was defined, whichever occurred earlier. In Part 2, we are currently evaluating the combination treatment of BNT152 and BNT153.

2. Oncology Cell Therapy Product Candidates

a) CAR-T-cell therapy - CAR-T

i. BNT211 for the Treatment of CLDN6+ Solid Tumors

BNT211 consists of two investigational medicinal products: our first CAR-T-cell product candidate, which targets CLDN6-positive solid tumors, in combination with an mRNA named CARVac encoding CLDN6. The CAR-T cells are equipped with a second-generation CAR of high sensitivity and specificity for the tumor-specific carcino-embryonic antigen CLDN6. CARVac is intended to support *in vivo* expansion of transferred CAR-T cells to increase their persistence and efficacy. As with *FixVac* and *iNeST*, CARVac is also based on a pharmacologically optimized-backbone equipped uRNA delivered in our proprietary RNA-LPX formulation. BNT211 has been granted Priority Medicines, or PRIME, designation by the EMA for the third- or later-line treatment of testicular germ cell tumors.

Ongoing Phase 1/2 Clinical Trial

An open-label, multi-center Phase 1/2 dose escalation and dose expansion basket clinical trial (NCT04503278) evaluating CLDN6 CAR-T cells with or without a CLDN6 CARVac in patients with CLDN6-positive relapsed or refractory advanced solid tumors, including ovarian and testicular cancers, is ongoing. The primary outcome measure of the trial is safety, with secondary efficacy outcome measures to include ORR, DCR and DOR.

- A data update from the ongoing clinical trial was provided at the 2023 ASCO Annual Meeting describing the new dose escalation of CLDN6 CAR-T cells with and without CLDN6 CARVac using an automated manufacturing process for treatment of relapsed/refractory solid tumors. CLDN6 CAR-T cells ± CLDN6 CARVac showed a manageable safety profile in-line with that of manually produced CLDN6 CAR-T cells. Encouraging signs of activity were observed, with dose-dependent expansion of CAR-T cells translating into ORR of 41% with 7 responses in 17 evaluable patients (ORR 75% at dose level 2).
- In October 2023, data from the manual manufacturing process were published in *Nature Medicine* (Mackensen, A. et al., 2023).
- A second data update from the ongoing clinical trial was presented at the 2023 ESMO Congress, describing the interim results from a repeat dose escalation of CLDN6 CAR-T cells manufactured with an automated process with and without CLDN6 CARVac vaccine for treatment of relapsed/refractory solid tumors. CLDN6 CAR-T cells ± CLDN6 CARVac demonstrated encouraging signs of clinical activity. In several patients co-administration of CARVac improved persistence of cancer-specific CAR-T cells. The rate of treatment-emergent adverse events (TEAEs) was dose-dependent. A Phase 2 trial evaluating BNT211 in patients with germ cell tumors is planned to start in 2024.

b) Neoantigen-Targeting T Cells

Our neoantigen-targeting T-cell stimulation platform can be utilized to develop product candidates across several neoantigen-targeting non-engineered and engineered T-cell therapies. Autologous, neoantigen-specific T cells are primed, activated and expanded *ex vivo* utilizing a proprietary antigen-specific T-cell induction protocol, *Neo-Stim*, to target either a personal set of neoantigens for each patient or a set of selected shared neoantigens. Our lead product candidate under this platform is our individualized neoantigen-targeting T-cell therapy, BNT221.

i. BNT221 for the Treatment of Cancer

BNT221 is our autologous, fully personalized, polyspecific T-cell therapy directed against selected sets of individual neoantigens. BNT221 is based on expanded neoantigen-specific memory T cells and induced naïve T cells. The proprietary stimulation process allows for the induction of T cells from the naïve compartment, as well as expansion of T cells from the memory compartment. Other product characteristics are (i) cells with high specificity profile towards the mutant epitope; (ii) cells exhibiting multiple effector functions; (iii) a product that contains both central and effector memory T cells; and (iv) cells that have cytotoxic response towards endogenously processed and presented antigens as well as recognition of autologous tumor. The neoantigens are selected using our proprietary *RECON* bioinformatics engine.

Ongoing Phase 1 Clinical Trial

A first-in-human Phase 1 dose escalation clinical trial (NCT04625205) evaluating BNT221 in patients with checkpoint inhibitor unresponsive or refractory metastatic melanoma is ongoing. The first portion of the trial consists of a monotherapy dose escalation of BNT221, for which recruitment and treatment of patients is complete. Currently, BNT221 is being dosed in combination with anti-PD-1 therapy after first-line treatment. Major objectives of this study include evaluation of the safety and feasibility of administering BNT221, as well as evaluations of immunogenicity and preliminary efficacy.

- The first monotherapy data from the dose escalation phase of this clinical trial were presented at the 2023 ESMO Congress and 2023 SITC Annual Meeting. These initial results demonstrated a manageable safety profile and signs of tumor regression in several patients with anti-PD-1 and anti-CTLA-4 pretreated advanced or metastatic melanoma.

3. Protein-based Therapeutic Product Candidates in Oncology

a) Next-Generation Immune Checkpoint Modulators

We and Genmab are developing antibodies that are designed to function as tumor-targeted and dual immunomodulators, applying Genmab's proprietary technologies in combination with our joint target identification and product concept expertise. BNT311/GEN1046 (acasanlimab), BNT312/GEN1042, BNT313/GEN1053, BNT314/GEN1059, BNT315/GEN1055, and BNT322/GEN1056 are partnered with Genmab as part of a 50:50 collaboration in which development costs and future profits are shared. We and Genmab have five product candidates currently in clinical development: BNT311/GEN1046 (acasanlimab, DuoBody PD-L1x4-1BB), BNT312/GEN1042 (DuoBody CD40x4-1BB), BNT313/GEN1053 (HexaBody-CD27), BNT314/GEN1059 (DuoBody-EpCAMx4-1BB), and BNT322/GEN1056 (target undisclosed). In October 2023, an Investigational New Drug Application (IND) was submitted for an additional product candidate, BNT315/GEN1055 (HexaBody-OX40) and the IND has been cleared by the U.S. FDA.

In March 2023, we and OncoC4 announced entry into a strategic collaboration, which includes joint development of BNT316/ONC-392 in a range of solid tumor indications, with the parties equally sharing development costs for such joint development studies. BioNTech holds the exclusive worldwide commercialization rights for this product candidate.

In November 2023, we announced an exclusive global license and collaboration with Biotheus under which we will be developing, manufacturing and commercializing Biotheus' bispecific antibody candidate BNT327/PM8002 globally ex-Greater China.

i. BNT311/GEN1046 (acasanlimab) a PD-L1x4-1BB Bispecific Antibody for the Treatment of Solid Tumors

BNT311/GEN1046 (acasanlimab), our jointly owned PD-L1x4-1BB product candidate, is a potential first-in-class bispecific antibody combining PD-L1 checkpoint inhibition with 4-1BB stimulation. BNT311/GEN1046 (acasanlimab) is being developed for the treatment of solid tumors using Genmab's proprietary DuoBody technology platform. We and Genmab are currently evaluating BNT311/GEN1046 (acasanlimab) in multiple clinical trials.

Ongoing Phase 2 Trial in Metastatic NSCLC

A Phase 2, multi-center, randomized, open-label clinical trial (NCT05117242) of BNT311/GEN1046 (acasanlimab) as monotherapy and in combination with pembrolizumab in patients with relapsed/refractory metastatic NSCLC and a tumor PD-L1 expression of tumor proportion score, or TPS, of $\geq 1\%$ after treatment with standard of care therapy with an immune checkpoint inhibitor is ongoing. The primary endpoint is ORR according to Response Evaluation Criteria in Solid Tumors, or RECIST v1.1. Secondary endpoints include DOR, TTR, PFS, OS and safety.

We are planning to share data from this clinical trial at a medical conference in 2024. Based on the data, we are engaging with health authorities on the design of a pivotal trial evaluating BNT311/GEN1046 (acasanlimab) in second line NSCLC.

Ongoing Phase 2 Trial in Advanced Endometrial Cancer

In September 2023, an open-label Phase 2 clinical trial (NCT06046274) in treatment-experienced patients with advanced (unresectable and/or metastatic) endometrial cancer was initiated to evaluate the safety and clinical activity of BNT311/GEN1046 (acasanlimab) in combination with pembrolizumab in these patients.

Ongoing Phase 1/2 Clinical Trial in Solid Tumors

In May 2019, we and Genmab initiated a Phase 1/2, multi-center, open-label clinical trial (NCT03917381) with multiple expansion cohorts evaluating BNT311/GEN1046 (acasnlimab) as monotherapy and in combination therapies in patients with multiple solid tumors. The trial is currently ongoing.

Ongoing Phase 1 Clinical Trial in Japanese Patients

In June 2021, we and Genmab initiated a Phase 1 open-label, dose escalation clinical trial (NCT04937153) evaluating the safety and pharmacokinetics of BNT311/GEN1046 (acasnlimab) as monotherapy and in combination with pembrolizumab in Japanese patients with multiple solid tumors. The trial is currently ongoing.

ii. BNT312/GEN1042, a CD40x4-1BB Bispecific Antibody for the Treatment of Solid Tumors

BNT312/GEN1042 is a jointly owned, novel, agonistic, bispecific antibody that combines targeting and conditional activation of the costimulatory molecules CD40 and 4-1BB on immune cells. BNT312/GEN1042 is being developed for the treatment of solid cancers using Genmab's proprietary DuoBody technology platform and our CD40 and 4-1BB antibodies. We and Genmab are currently evaluating BNT312/GEN1042 in multiple clinical trials.

Ongoing Phase Clinical Trials

A Phase 1/2 dose-escalation clinical trial (NCT04083599) with expansion cohorts evaluating safety and anti-tumor activity of BNT312/GEN1042 as monotherapy and in combination therapies in patients with solid tumors is ongoing. We and Genmab are anticipating data needed to determine next steps for this program in 2024.

In April 2023, we and Genmab initiated an open-label Phase 1/2 clinical trial (NCT05491317) evaluating the safety and clinical activity of BNT312/GEN1042 in combination with radiotherapy with or without pembrolizumab in patients with metastatic solid tumors.

In November 2023, we and Genmab initiated a Phase 1 clinical trial (NCT06057038) in Japan evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics and antitumor activity of BNT312/GEN1042 monotherapy and in combination with pembrolizumab with or without chemotherapy in patients with multiple solid tumors.

iii. BNT313/GEN1053, an Agonistic Hexabody-CD27 Antibody for the Treatment of Malignant Solid Tumors

BNT313/GEN1053 is a novel CD27 antibody with an IgG Fc domain engineered to induce clustering of CD27 on the plasma membrane of T cells with the aim of enhancing T-cell activation, proliferation and differentiation without depleting T cells. In preclinical studies, BNT313/GEN1053 increases T-cell activation, proliferation, cytokine secretion and cytotoxic activity.

Ongoing Phase 1/2 Clinical Trial

A Phase 1/2 clinical trial (NCT05435339) evaluating the safety, tolerability and preliminary efficacy of BNT313/GEN1053 as monotherapy in patients with advanced solid tumors is currently recruiting.

iv. BNT314/GEN1059, an EpCAMx4-1BB Bispecific Antibody for the Treatment of Advanced or Metastatic Solid Tumors

BNT314/GEN1059 is a potential first-in-class bispecific antibody product candidate, using Genmab's proprietary DuoBody technology platform designed to boost antitumor immune responses through EpCAM-dependent 4-1BB agonistic activity.

At the 2023 ESMO Congress, we and Genmab presented preclinical data describing the mechanism of action of BNT314/GEN1059. In preclinical studies, BNT314/GEN1059 was shown to enhance T-cell activation, proliferation, and effector functions *in vitro* and *ex vivo*, and to promote antitumor activity *in vivo*. These results suggest that BNT314/GEN1059 may boost antitumor immunity in cancer patients with EpCAM-positive tumors.

A first-in-human Phase 1/2 clinical trial (NCT06150183), which we are sponsoring, is currently recruiting to investigate the safety and preliminary antitumor activity of BNT314/GEN1059 in patients with advanced or metastatic solid tumors.

v. *BNT315/GEN1055, a HexaBody-OX40 Antibody for the Treatment of Advanced Solid Tumors*

At the 2023 ESMO Immuno-Oncology Congress, we and Genmab presented preclinical data describing BNT315/GEN1055. In preclinical studies, BNT315/GEN1055 exhibited FcγR-crosslinking-independent OX40 agonist activity, a unique mechanism of action that is distinct from conventional IgG1 OX40 agonists. BNT315/GEN1055 enhanced T-cell activation and proliferation *in vitro* and showed antitumor activity *in vivo*.

A first-in-human clinical trial is planned to start in the first half of 2024 to evaluate the clinical safety and preliminary efficacy of BNT315/GEN1055 in patients with advanced solid tumors.

vi. *BNT322/GEN1056, an Antibody for the Treatment of Solid Tumors*

BNT322/GEN1056 is an antibody product candidate we are co-developing with Genmab for the treatment of solid tumors and for potential use in combination with other products. A first-in-human Phase 1 clinical trial (NCT05586321) of BNT322/GEN1056 in patients with advanced solid tumors is currently ongoing.

vii. *BNT327/PM8002, a Bispecific Antibody Candidate Targeting PD-L1 and VEGF, in Collaboration with Biotheus*

BNT327/PM8002 is an anti-VEGF-A antibody candidate fused to a humanized anti-PD-L1 VHH being developed in collaboration with Biotheus. BNT327/PM8002 is currently being evaluated in Phase 1 and Phase 2/3 clinical trials in China to assess the efficacy and safety of the candidate as monotherapy or in combination with chemotherapy in various indications.

- Data from a Phase 1/2 trial in advanced solid tumors presented in 2023 demonstrated that BNT327/PM8002 as monotherapy was observed to have antitumor activity and a manageable safety profile.
- Data from Phase 2 trials in patients with small cell lung cancer, or SCLC, and TNBC presented in 2023 demonstrated that BNT327/PM8002 in combination with chemotherapy was observed to have encouraging antitumor activity and an acceptable toxicity profile as second- and first-line therapy, respectively.

Additional data readouts, both in monotherapy and combination, are expected across a range of solid tumors in 2024.

viii. *BNT316/ONC-392 (gotistobart), an Anti-CTLA-4 Monoclonal Antibody Candidate in Development in Collaboration with OncoC4*

BNT316/ONC-392 (gotistobart) is a next-generation anti-CTLA-4 antibody candidate. CTLA-4 is a molecule which inhibits T-cell immune response and reduces the activity of T cells in recognizing and eliminating cancer cells. Blocking CTLA-4 preserves T-cell activity and enhances anti-tumor activity. Our next-generation anti-CTLA-4 antibody candidate BNT316/ONC-392 (gotistobart) was designed to preserve CTLA-4 recycling and thus function of regulatory T cells in the peripheral tissues.

Ongoing Phase 3 Clinical Trial in Metastatic, Immunotherapy-resistant NSCLC

In June 2023, a Phase 3 clinical trial (NCT05671510) was initiated to evaluate BNT316/ONC-392 (gotistobart) as monotherapy in patients with metastatic NSCLC whose disease progressed on anti-PD-1/PD-L1 antibody based therapy. The trial initiation followed the U.S. FDA Fast Track Designation granted in 2022 and is based on Phase 1/2 safety and efficacy data for the monotherapy in metastatic, immunotherapy-resistant NSCLC. The two-stage Phase 3 clinical trial will assess the efficacy and safety of BNT316/ONC-392 (gotistobart) as monotherapy compared to the standard-of-care chemotherapy (docetaxel) in patients with metastatic NSCLC that progressed under previous PD-(L)1-inhibitor treatment. The primary endpoint is OS. Secondary endpoints include ORR, PFS and safety. Approximately 600 patients are planned to be enrolled at clinical sites in the United States, China, Australia, South Korea, Türkiye, Canada, the UK and the EU countries Germany, Spain, Italy, Belgium and the Netherlands.

Ongoing Phase 2 Clinical Trial in Platinum-resistant Ovarian Cancer

An open-label, randomized Phase 2 clinical trial (NCT05446298) evaluating BNT316/ONC-392 (gotistobart) therapy in combination with pembrolizumab in platinum-resistant ovarian cancer is ongoing. The clinical trial is evaluating two doses of BNT316/ONC-392 (gotistobart) in combination with a fixed dose of pembrolizumab in participants with ovarian cancer who are resistant to platinum-based chemotherapy and have disease progression after one line of therapy containing bevacizumab. The primary endpoints are ORR and safety. Secondary endpoints include DOR, DCR, PFS and OS.

Ongoing Phase 1/2 Clinical Trial in Advanced or Metastatic Solid Tumors

A first-in-human Phase 1/2 open-label dose escalation clinical trial (NCT04140526) evaluating BNT316/ONC-392 (gotistobart) as monotherapy and in combination with pembrolizumab in patients with advanced or metastatic solid tumors is ongoing.

- At the 2023 ASCO Annual Meeting and the 2023 SITC Annual Meeting, we and OncoC4 presented data from expansion cohorts in the ongoing Phase 1/2 clinical trial that demonstrated BNT316/ONC-392 (gotistobart) was generally safe and well tolerated and TEAEs were manageable. The data also demonstrated encouraging clinical activity in patients with immunotherapy-resistant NSCLC.

Ongoing Phase 1/2 Clinical Trial in Metastatic Castration Resistant Prostate Cancer

An open-label, randomized Phase 1/2 clinical trial (NCT05682443) assessing the efficacy and safety of BNT316/ONC-392 (gotistobart) in combination with the radioligand therapy, lutetium Lu 177 vipivotide tetraxetan (Novartis's Pluvicto), in patients with mCRPC who have progressed on an androgen receptor, or AR pathway inhibitor was initiated in 2023 and is recruiting patients. In December 2023, the first patient was treated as part of the trial. The primary endpoint is PFS. The trial is expected to enroll approximately 144 patients at clinical trial sites in the United States.

b) Targeted Cancer Antibodies

i. BNT321 for the Treatment of Pancreatic Cancer

BNT321 is a high affinity, fully human IgG1 monoclonal antibody targeting sialyl Lewis A (sLea), an epitope on CA19-9 which is expressed in pancreatic and other gastrointestinal cancers. sLea plays a role in tumor adhesion and metastasis formation and is a marker of an aggressive cancer phenotype.

Ongoing Phase 1/1b Clinical Trial

A Phase 1/1b trial (NCT02672917) is evaluating BNT321 monotherapy and in combination with mFOLFIRINOX in patients with advanced PDAC and other CA19-9+ tumors.

- Data from the trial were presented at the ASCO Gastrointestinal Cancer Symposium 2024. Preclinically, BNT321 binding was observed to be highly specific and restricted to cancer tissues with sLea expression. The most frequent dose-limiting toxicities, or DLTs, for both monotherapy and for mFOLFIRINOX combination therapy are hepatic transaminase elevations. DLTs generally occur in cycle 1 and do not preclude subsequent BNT321 administration at reduced doses. BNT321 in combination with mFOLFIRINOX was tolerable for multiple cycles. Clinical activity (27% PR, RECIST) was observed in patients receiving the combination as first or subsequent line therapy for advanced disease.

Ongoing Phase 1/2 Clinical Trial

A Phase 1/2 trial (NCT06069778) evaluating the safety, tolerability, and efficacy of BNT321 in combination with mFOLFIRINOX as an adjuvant therapy following curative resection in patients with PDAC has been initiated.

c) Antibody Drug Conjugates (ADCs)

In 2023, we broadened our access to a new technology - ADCs - because we believe this technology has the potential to replace highly toxic chemotherapy regimens and become a potential new combination backbone for cancer treatment. Our growing ADC pipeline now includes ADCs directed against four distinct targets and is of interest for a broad range of cancer types.

In April 2023, we announced a collaboration with DualityBio for exclusive licenses to two investigational ADC assets (BNT323/DB-1303 and BNT324/DB-1311) directed against targets expressed in a broad range of human cancers. In

August 2023, we signed another exclusive agreement with DualityBio to develop, manufacture and commercialize an additional ADC, BNT325/DB-1305.

In October 2023, we signed a strategic research collaboration and worldwide license agreement with MediLink Therapeutics for the development of a next-generation ADC, BNT326/YL202.

i. BNT323/DB-1303, an ADC in Development in Collaboration with DualityBio

BNT323/DB-1303 is a topoisomerase-1 inhibitor-based ADC directed against Human Epidermal Growth Factor Receptor 2, or HER2, a target that is over-expressed in a variety of cancers and contributes to the aggressive growth and spread of cancer cells. The program received Fast Track Designation from the U.S. FDA for endometrial cancer in January 2023. In December 2023, the U.S. FDA granted Breakthrough Therapy designation for BNT323/DB-1303 for the potential treatment of advanced endometrial cancer in patients who progressed on or after treatment with immune checkpoint inhibitors. With the Breakthrough Therapy designation, we seek to expedite the further development of BNT323/DB-1303 in this indication.

Ongoing BNT323/DB-1303 Phase 3 Clinical Trial in Advanced or Metastatic Hormone Receptor-positive, or HR+, HER2-low Breast Cancer

An ongoing randomized, multi-center, open-label Phase 3 clinical trial (NCT06018337) is recruiting to evaluate BNT323/DB1303 versus the investigator's choice of chemotherapy in advanced or metastatic HR+, HER2-low breast cancer subjects whose disease has progressed on at least two lines of prior endocrine therapy or within six months of first line endocrine therapy + cyclin-dependent 4/6 (CDK4/6) inhibitor and no prior chemotherapy. The first patient was dosed in January 2024. The trial aims to enroll approximately 532 patients. The primary endpoint is PFS. Secondary endpoints include OS, ORR, DCR, DOR and safety as well as patient-reported outcomes.

Ongoing BNT323/DB-1303 Phase 1/2 Clinical Trial in Advanced or Metastatic HER2-expressing Solid Tumors

BNT323/DB-1303 is being evaluated in an ongoing multi-center, non-randomized, open-label, multiple dose, first-in-human Phase 1/2 clinical trial (NCT05150691) in patients with advanced/unresectable, recurrent, or metastatic HER2-expressing solid tumors, including HER2-expressing breast cancer and endometrial cancer. Most patients in this trial were recruited in the United States.

- A potential registrational single-arm trial enrolling HER2-expressing (IHC3+, 2+, 1+ or ISH-positive) patients with endometrial carcinoma is ongoing and plans to recruit 140 patients.
- We and DualityBio presented data from the ongoing trial at the 2023 ASCO Annual Meeting from patients with multiple solid tumors, including breast cancer HER2-expressing tumors. BNT323/DB-1303 was well tolerated with no DLT, and no TEAEs associated with death were observed. Preliminary antitumor activity was observed in heavily pretreated HER2-expressing patients with a median of seven prior systemic treatment regimens, including other HER2 ADCs.
- In September 2023, data from the ongoing trial were presented at the European Society of Gynecological Oncology (ESGO) Congress focusing on patients with advanced/metastatic endometrial cancer. BNT323/DB-1303 was observed to have a manageable safety profile, and no new safety signals were observed. Antitumor activity was observed in patients (n=17) with advanced, recurrent or metastatic HER2-expression endometrial cancer following treatment with BNT323/1303, with an ORR of 58.8% and DCR of 94.1%.

ii. BNT324/DB-1311, an ADC in Development in Collaboration with DualityBio

BNT324/DB-1311 is a topoisomerase-1 inhibitor-based ADC directed against B7H3.

Ongoing BNT324/DB-1311 Phase 1/2 Clinical Trial in Advanced Solid Tumors

A first-in-human, multi-center, open-label, dose escalation and dose-expansion Phase 1/2a clinical trial evaluating the safety and tolerability of BNT324/DB-1311 in patients with advanced solid tumors has been initiated and the first patient was dosed in September 2023.

iii. BNT325/DB-1305, an ADC in Development in Collaboration with DualityBio

BNT325/DB-1305 is a topoisomerase-1 inhibitor-based ADC directed against TROP2. In January 2024, we and DualityBio received Fast Track Designation for BNT325/DB-1305 from the U.S. FDA for the treatment of patients with platinum-resistant ovarian epithelial cancer, fallopian tube, or primary peritoneal cancer in patients who have received one to three prior systemic treatment regimens.

Ongoing BNT325/DB-1305 Phase 1/2 Clinical Trial in Advanced Solid Tumors

A multi-center, non-randomized, open-label, multiple-dose, first-in-human Phase 1/2a clinical trial (NCT05438329) evaluating BNT325/DB-1305 in patients with advanced solid tumors is ongoing.

- In October 2023, first-in-human data from the ongoing trial were presented at the ESMO Congress, in which a manageable safety profile was observed at lower dose levels. Encouraging preliminary activity of BNT325/DB-1305 was observed with an ORR of 30.4% (7/23) and DCR of 87.0% (20/23), both unconfirmed at the time of the presentation. 13 NSCLC patients had an unconfirmed ORR of 46.2% (6/13), and an unconfirmed DCR of 92.3% (12/13).
- In November 2023, two new cohorts were added to the study: a cohort to evaluate BNT325/DB-1305 monotherapy in cervical cancer and a cohort to assess the combination of BNT325/DB-1305 with pembrolizumab in NSCLC.

iv. BNT326/YL202, an ADC in Development in Collaboration with MediLink Therapeutics

BNT326/YL202 is a topoisomerase-1 inhibitor-based ADC directed against HER3. HER3 is a target that is overexpressed in various cancer types, such as NSCLC and breast cancer and is closely associated with tumor metastasis and disease progression. Furthermore, HER3 expression is upregulated after frontline drug therapy, making it an adequate target for cancer treatment resistance.

Ongoing BNT326/YL202 Phase 1 Clinical Trial in NSCLC and Breast Cancer

A multi-center, open-label, first-in-human Phase 1 clinical trial (NCT05653752) evaluating BNT326/YL202 as a later-line treatment in patients with locally advanced or metastatic epidermal growth factor receptor, or EGFR-mutated NSCLC or HR-positive and HER2-negative breast cancer is ongoing.

4. Oncology Small Molecule Immunomodulator Product Candidates

i. BNT411, a Small Molecule TLR7 Agonist for the Treatment of Solid Tumors, including SCLC

BNT411 is a TLR7 agonist that is designed to activate both the adaptive and innate immune system through the TLR7 pathway. This activity and the release of cytokines and chemokines are designed to result in the potent stimulation of antigen-specific CD8⁺ T cells, B cells and innate immune cells such as natural killer cells, or NK cells, and macrophages.

Ongoing Phase 1/2 Trial

A Phase 1/2, first-in-human, open-label, dose escalation trial (NCT04101357) with expansion cohorts evaluating safety, pharmacokinetics, progression of disease and preliminary efficacy of BNT411 as monotherapy in patients with solid tumors and in combination with atezolizumab, carboplatin and etoposide in patients with chemotherapy-naïve ES-SCLC is ongoing.

B. Infectious Disease Programs

1. Next-Generation COVID-19 Vaccine

i. BNT162b5/6/7

In collaboration with Pfizer, we are developing vaccine candidates with a stabilized antigen design aimed to increase the magnitude and breadth of antibody responses to better protect against COVID-19.

- A randomized, active controlled, observer-blind Phase 2 clinical trial to evaluate the safety, tolerability and immunogenicity of stabilized spike antigen vaccine candidates is ongoing.

ii. BNT162b2 + BNT162b4

In collaboration with Pfizer, we are aiming to develop a vaccine candidate that enhances and broadens SARS-CoV-2 T-cell responses. BNT162b4 is a next-generation COVID-19 vaccine component designed to elicit T-cell immunity across epitopes. BNT162b4 encodes variant-conserved, immunogenic segments of the SARS-CoV-2 nucleocapsid, membrane, and ORF1ab proteins, targeting diverse human leukocyte antigen, or HLA, alleles.

- A Phase 1 clinical trial to evaluate the safety, tolerability and immunogenicity of BNT162b4, in combination with BNT162b2 is ongoing.

2. COVID-19 – Influenza Combination mRNA Vaccine Program – BNT162b2 + BNT161

In October 2022, we and Pfizer initiated a Phase 1/2 open-label, dose-finding trial (NCT05596734) to evaluate the safety, tolerability and immunogenicity of a combination of the COVID-19 and influenza mRNA vaccines in 180 healthy adults 18 to 64 years of age. The combination vaccine consists of our Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine and Pfizer's quadrivalent modified RNA (modRNA) influenza vaccine.

In December 2022, we and Pfizer announced that the companies received Fast Track Designation from the U.S. FDA for the mRNA-based combination vaccine candidate for influenza and COVID-19.

- In October 2023, we and Pfizer announced top-line results from a Phase 1/2 clinical trial (NCT06178991) evaluating the safety, tolerability and immunogenicity of mRNA-based combination vaccine candidates for influenza and COVID-19 among healthy adults 18 to 64 years of age. In the clinical trial, the vaccine candidates were compared to licensed influenza vaccines and the Pfizer-BioNTech COVID-19 Omicron BA.4-5 adapted bivalent vaccine given separately at the same visit.
- The data from the trial demonstrated robust immune responses to influenza A, influenza B and SARS-CoV-2 strains, as well as a safety profile consistent with the safety profile of the companies' COVID-19 vaccine.
- A pivotal Phase 3 clinical trial (NCT06178991) was initiated in December 2023 and aims to enroll 7,500 healthy subjects 18 to 64 years old of age. Further development is subject to entering into a definitive agreement.

3. Influenza Vaccine Program – BNT161

In 2018, we and Pfizer entered into an agreement to collaborate on an mRNA program to develop an influenza vaccine for an initial period of three years, which ended in 2021. Pfizer has since the sole responsibility, authority and control of the development, manufacturing and commercialization of all candidates and products related to the program. Upon potential approval and commercialization, we are eligible to receive a royalty on Pfizer's sales.

- A Pfizer-initiated, randomized Phase 3 clinical trial to evaluate the efficacy, safety, tolerability and immunogenicity of a quadrivalent modRNA influenza vaccine candidate is ongoing.

4. Herpes Simplex Virus (HSV) Vaccine Program – BNT163

We have a research collaboration with the University of Pennsylvania under which we have the exclusive option to develop and commercialize mRNA vaccine candidates against up to 10 infectious disease indications. As part of this collaboration, we are developing a HSV vaccine candidate.

A first-in-human, controlled Phase 1 clinical trial (NCT05432583) evaluating the safety, tolerability and immunogenicity of BNT163, an HSV vaccine candidate for the prevention of genital lesions caused by HSV-2, and potentially HSV-1, is ongoing. Dose escalation Part A has been completed, with the last subject visit in December 2023, and Part B (safety and dose evaluation) is opening for enrollment across sites in the United States.

5. Tuberculosis Vaccine Program - BNT164

Two randomized, controlled, dose-finding Phase 1 clinical trials evaluating BNT164 are ongoing (NCT05537038, Germany and NCT05547464, Republic of South Africa). The clinical trials' first subjects were dosed in April and August 2023, respectively. Both clinical trials will assess the safety, reactogenicity and immunogenicity of two mRNA vaccine candidates against tuberculosis. This program is run in partnership with the Bill & Melinda Gates Foundation.

6. Malaria Vaccine Program – BNT165

Our malaria program aims to develop a well-tolerated and highly effective mRNA vaccine with durable immunity to prevent blood-stage *P. falciparum* malaria infection, thereby aiming to reducing morbidity, mortality and onward transmission, and to develop sustainable vaccine production and supply solutions on the African continent. We plan to assess several vaccine candidates, featuring components of known targets such as circumsporozoite protein (CSP), conserved, immunogenic segments of liver stage-expressed proteins as well as other antigens.

- A first-in-human Phase 1 clinical trial (NCT05581641) to evaluate the safety, tolerability and exploratory immunogenicity of a vaccine candidate had its last subject last dosed in September 2023. Follow-up is ongoing until September 2024.
- A randomized, dose escalation Phase 1/2 (NCT06069544) trial to evaluate the safety, tolerability, immunogenicity and efficacy of a second investigational RNA-based vaccine candidate in a controlled human malaria infection model has been initiated. The first subject was dosed in November 2023.

7. Mpox Vaccine Program – BNT166

Our fully owned BNT166 program aims to develop an effective, well-tolerated and accessible vaccine for the prevention of mpox. The multivalent BNT166 mRNA vaccine candidates encode surface antigens that are expressed in the two infectious forms of the mpox virus to efficiently fight virus replication and infectivity. The program is supported through a partnership with the Coalition for Epidemic Preparedness Innovations, or CEPI, to provide equitable access to the vaccine, if successfully developed and approved, in low- and middle-income countries.

- A Phase 1/2 clinical trial (NCT05988203) evaluating the safety, tolerability, reactogenicity and immunogenicity of an mRNA-based multivalent vaccine candidate has been initiated and the first subject was dosed in October 2023. The trial aims to enroll 64 healthy subjects with and without prior history of known or suspected smallpox vaccination.

8. Shingles Vaccine Program – BNT167

We and Pfizer are developing the first mRNA-based vaccine candidate against shingles. While there are currently approved vaccines for shingles, the goal is to develop an mRNA vaccine candidate that potentially shows high efficacy, better tolerability and is more efficient to produce globally.

A randomized, controlled, dose-selection Phase 1/2 clinical trial (NCT05703607) to evaluate the safety, tolerability, and immunogenicity of BNT167 in up to 900 healthy volunteers, 50 through 69 years of age, was initiated in February 2023.

9. Anti-bacterial Programs

BioNTech R&D (Austria) GmbH is a wholly owned subsidiary of BioNTech SE focused on the development of novel anti-bacterial drugs to treat persistent bacterial infections. These development programs are based on the proprietary LysinBuilder platform, which allows the targeted development of precision anti-bacterials. The development pipeline focuses on chronic bacterial infections where antibiotics fail to cure or destroy the natural microbiomes.

VI. The mRNA Technology

In the last decade, mRNA has progressed into a promising new class of medicine, with the potential to treat a wide variety of diseases with high unmet medical needs. mRNA is a long, polymeric molecule, composed of four different building blocks called nucleotides. In mRNA, hundreds or thousands of these nucleotides are linked in a unique order to convey genetic information to cells, where it is used to express proteins with biological effects.

Since the COVID-19 pandemic, mRNA-based immunization for the prevention of infectious diseases is considered an innovative alternative to conventional vaccine approaches. mRNA has shown the potential to elicit potent protective immune responses against various pathogens and may offer advantages over the use of live and inactivated virus vaccines, subunit vaccines, and other nucleic-acid-based vaccine formats. According to Beissert et al (2020), “RNA is non-infectious, non-integrating and, by virtue of rapid degradation by normal cellular processes, is only transiently active. RNA can be administered repeatedly both to prime and to boost immune responses and is not limited by anti-vector immunity. Moreover, the RNA backbone engages pattern recognition receptors in the host cell, thereby naturally adjuvanting the response to the encoded immunogen.” According to the same study, mRNA can also enable “rapid, cost-efficient, cell- and animal-material-free, scalable production without the use of egg- or cell-based culture. Thus, RNA may facilitate how vaccines are made and has the potential to enable a rapid response to emerging infections.”

Synthetic mRNA can be engineered to resemble mature and processed mRNA molecules that naturally occur in the cytoplasm of eukaryotic cells and can be used to transiently deliver proteins. Established mRNA manufacturing technologies can be quickly adapted to produce mRNAs of different sequences, permitting the rapid development of mRNAs with the potential to address a variety of different conditions, including cancer, infectious disease, and rare diseases. Our mRNA pipeline addresses each of these therapeutic areas.

A. General Principles of mRNA Pharmacology

As a drug, manufactured mRNA provides instructions to a target cell to produce particular encoded protein(s) with a desired prophylactic or therapeutic effect. Based on these instructions, the proteins will be either secreted or remain intracellular. The mRNA drug will eventually be degraded and eliminated from the body.

Our mRNA drugs are synthesized in a cell-free system by *in vitro* transcription from a DNA template. This template encodes all of a functional mRNA’s structural elements with the exception of the 5’ cap structure, which is co-transcriptionally incorporated. After *in vitro* transcription is performed, the template is then digested by DNases and the mRNA is purified by conventionally-used methods for isolating nucleic acids. The mRNA molecule comprises:

- an open reading frame, or ORF, which encodes for the protein of interest;
- untranslated regions, or UTRs, which flank the ORF; and
- the cap and the poly(A) tail, which are the two terminal structures of the linear mRNA, and are responsible for increased stability and translational efficiency of mRNA.

The mRNA drug needs to be appropriately formulated in order to protect mRNA molecules against enzymatic degradation by ribonucleases and to facilitate their delivery to the target cells. The formulation is selected based on the intended application and route of delivery. After uptake into the target cell, the mRNA molecules are loaded into ribosomes, where translation into protein takes place. Subsequently, the mRNA is degraded by cellular mechanisms. Proteins encoded by the mRNA can be secreted or maintained in or on the cell. Encoded proteins can perform functions in the body, for example, replacing activities that are deficient, or they can trigger immune responses, for example by acting as antigens (as in the case of vaccines), or by directing the immune system to a target of interest (as in the case of many therapeutic antibodies). Also, proteins encoded by the mRNA are processed by the cellular machinery and can be displayed by specialized complexes, namely MHC I or MHC II complexes, to trigger T cell responses to epitopes present within them. These complexes present the epitopes to immune cells to provoke the desired immune response. In the case of other mRNA applications, the mRNA encodes proteins that are secreted from the cells, such as antibodies, and function extracellularly.

The structural elements of the mRNA have an impact on its performance. This includes potential immunogenicity, efficiency of translation and molecular stability. We leverage our extensive experience to design, synthesize, manufacture and formulate our therapeutic mRNA, and to adapt its composition to suit the desired application.

- The cap is added to the 5’ end of the mRNA during its synthesis. Our studies have demonstrated that incorporation of a unique cap analogue into the mRNA helps to achieve superior translational performance by stabilizing the mRNA molecule and directing the immune response.
- The composition and structure of the 5’ and 3’ untranslated regions of the mRNA molecule are important determinants of the intracellular stability of mRNA. As a result of rigorous screening of different mRNA sequences, we identified specific UTRs that promote increased protein translation for long duration.

- We have performed extensive research on the structure of the poly(A) tail and the translational performance of mRNA and customized our template design accordingly.

The translational performance of mRNA can be increased by reducing contaminating double-stranded RNA, or dsRNA, from the mRNA. We have extensive expertise in different mRNA purification procedures. We have also invented a novel mRNA purification method that greatly impacts translatability of our mRNA. Depending on the protein characteristics needed for treatment of a disease, we optimize the DNA template through a proprietary codon optimization process, changing the nucleotide sequence of the template without altering the amino acid composition of the encoded protein. We make further adjustments during mRNA production to minimize the occurrence of dsRNA by-products. We believe fine-tuning the respective molecules provides a great benefit to the purpose-adapted performance of our mRNA.

B. mRNA Formats

1. Optimized Uridine mRNA (uRNA)

The nucleotide sequence of mRNA determines the amino acid sequence of the protein. In addition, the nature of nucleosides used for production of mRNA drugs can also influence recognition of the molecule by the immune system. Presence of naturally occurring uridine (U) in our optimized uridine mRNA makes it immunogenic by activating immune sensors. We have further optimized our uridine mRNA for immunogenicity of the encoded antigen (augmented presentation on MHC I and MHC II) and pharmacological activity (enhanced stability and translational efficiency). Immunogenicity of the mRNA is an added benefit when mRNA is used for immunotherapy applications, by acting as an immunotherapy adjuvant. We believe this makes our therapeutics for iNeST and *FixVac* even more potent.

2. Nucleoside-modified mRNA (modRNA)

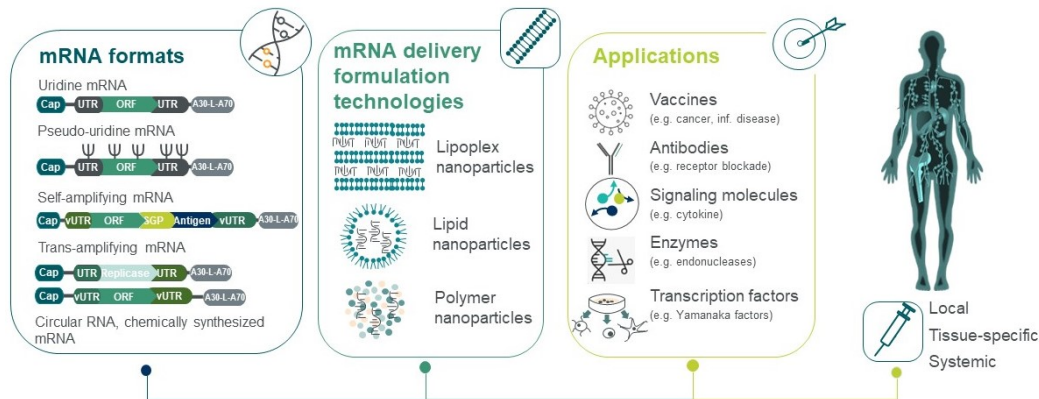
Immunogenic reaction against mRNA drugs needs to be avoided in applications where therapeutic proteins are produced, such as in our *RiboMab* and *RiboCytokine* platforms. We have profound expertise in incorporating naturally-occurring modified nucleosides into our therapeutic mRNAs. We have demonstrated that the presence of a variety of modified nucleosides in the manufactured mRNA suppresses its intrinsic immune activation, while leading to superior protein production for long duration. Deimmunizing mRNA by incorporating modified nucleosides helps to avoid the production of anti-drug antibodies and to broaden the therapeutic application of these types of mRNA drugs. We believe this customization has resulted in therapeutic mRNA that is both potent and well tolerated.

3. Self-amplifying mRNA (saRNA)

Our self-amplifying mRNA, or saRNA, drugs use the concept of viral mRNA replication, while not being infectious, disease-causing agents themselves. saRNA resembles conventional mRNA, encoding the protein of interest, but it also encodes an RNA-dependent RNA-polymerase, called replicase, that multiplies part of the mRNA within the target cell. Thus, lower amounts of saRNA are needed compared to a regular mRNA to obtain the same amount of active protein. As we have demonstrated, our saRNA ensures high levels of sustained antigen production with a small amount of initial mRNA input. Our scientific team has designed this mRNA technology to act as a potent tool for prophylactic vaccination, with the potential for application in infectious diseases.

4. Trans-amplifying mRNA (taRNA)

We have expanded on our self-amplifying mRNA capabilities and developed a novel mRNA amplification technology which separates amplification of the target mRNA and the replicase encoding mRNA. This advancement broadens the spectrum of applications by making the development of therapeutic and prophylactic mRNAs even more flexible, as the replicase can amplify mRNA encoding of not only one protein, but several different ones. In the case of vaccines, this allows us to produce the replicase in advance for use with different vaccines. Our trans-amplifying mRNA is a proprietary mRNA format that we believe is particularly well-suited for prophylactic vaccines to prevent infectious diseases. We believe that taRNA-based split-vector systems may be advantageous over saRNA with regard to safety, versatility, and manufacturing.



mRNA offers a broad technology toolbox: We have developed and optimized mRNA formats and delivery formulations for their potency and performance, each optimized for different therapeutic applications.

C. mRNA Delivery Formulation Technologies

We have deep and broad expertise in the targeted delivery of mRNA therapeutics. We are convinced that development of suitable delivery formulations in conjunction with our own therapeutic mRNAs is a key competitive advantage.

Our main mRNA delivery formulations, each designed for different functions and optimized for therapeutic product needs, are described below:

1. Lipoplex nanoparticles or RNA-LPX formulation

Our lipoplex formulation, or LPX, embeds the mRNA between a lipid bilayer, and is used for our *FixVac* and *iNeST* platforms. We use a proprietary size- and charge-based non-viral mRNA lipoplex that we developed to deliver mRNA to dendritic cells in lymphoid compartments (such as the spleen) for optimal antigen presentation and immune response activation. A synchronized adjuvant effect is mediated by TLR7-triggering and type-I interferon-driven innate and adaptive immune stimulation. Our RNA-LPX formulation allows for intravenous administration of our investigational mRNA cancer immunotherapies. RNA-LPX protects mRNA from degradation outside of the cell and mediates its efficient uptake and expression of encoded antigens in various dendritic cell, or DC, populations. Our RNA-LPX technology is designed to deliver multiple antigens in parallel, enabling the induction of poly-specific T-cell responses. We have demonstrated in the clinic that systemic DC targeting by mRNA cancer immunotherapies can result in potent activity against shared tumor-associated antigens at very low doses. Consequently, less material would be required for treating high patient numbers, making manufacturing potentially more cost-effective.

2. Lipid nanoparticle, or LNP, formulation

For other applications, we encapsulate our mRNA in lipid nanoparticles, or LNPs. These formulations are suitable for our *RiboMab*, *RiboCytokine* and prophylactic vaccines against infectious disease.

Our COVID-19 vaccines are based on an RNA-LNP platform of nucleoside modified RNA, which has blunted innate immune sensor activating capacity and thus augmented antigen expression. Our COVID-19 vaccines are formulated in LNPs. Encapsulation into LNPs enables transfection of the RNA into host cells after intramuscular injection. These LNPs are composed of four different lipids in a defined ratio. During the mixing of the RNA and the dissolved lipids, the lipids form nanoparticles encapsulating the RNA. After injection, the LNPs are taken up by the cells, and the RNA is released into the cytosol. In the cytosol, the RNA is translated to the encoded viral protein.

3. Polymer nanoparticles

Our portfolio also comprises polyplexes, in which the mRNA is bound to a polymer and then forms nanoparticles, which are being utilized in certain of our discovery programs.

D. mRNA Platforms

We are developing multiple mRNA-based therapeutics in the oncology space, including mRNA cancer vaccines (e.g., *FixVac* and *iNeST*), *RiboMabs*, and *RiboCytokines*, using different RNA formats and delivery formulations. We have also implemented mRNA platforms for the development of infectious disease vaccines.

Importantly, each of these platforms enables the development of multiple pharmaceutical product candidates or programs.

	mRNA platform	Drug target	mRNA format	Delivery formulation
	5 platforms	Broad range of targets	4	2
Oncology	iNeST	Neoepitopes	uRNA	RNA-LPX
	FixVac	Shared antigens	uRNA	RNA-LPX
	RiboMabs	mAb targets	modRNA	LNPs
	RiboCytokines	Cytokines	modRNA	LNPs
Infectious diseases	Prophylactic vaccines	Pathogens	saRNA, taRNA, modRNA	LNPs

Our mRNA Platforms. We have multiple mRNA-based platforms utilizing different mRNA formats and delivery formulations that are directed at a range of biological targets in oncology and infectious and rare diseases.

VII. Sales, Marketing and Distribution

Our commercial organization focuses on supporting sales of our COVID-19 vaccine in Germany and Türkiye. Our commercial organization is responsible for promoting our products to health care providers and providing information to stakeholders, including governmental organizations, in Germany and Türkiye.

As a result of our partnership with Pfizer, under which our commercialization responsibilities are limited to Germany and Türkiye, we are able to maintain a lean fixed cost base for our COVID-19 vaccine business.

Our commercial organization is also responsible for preparing and obtaining reimbursement from third-party payors, including governmental organizations, for our COVID-19 vaccine.

We aim to build a specialized oncology sales force in major markets, including North America and Europe, while leveraging our commercial partners for co-commercialization. We are working towards being commercial-ready in oncology by the end of 2025, in anticipation of potential commercial oncology launches as soon as 2026, if approved.

VIII. Manufacturing

We are building a fully integrated biotechnology company, with operations spanning from research through clinical development, manufacturing, and sales and marketing. To successfully bring individualized immunotherapies and vaccines to people around the world, we believe that it is crucial to have in-house manufacturing capabilities that can be efficiently scaled for global clinical and commercial distribution. We have several manufacturing sites capable of developing automated production processes for on-demand production of our investigational therapies and vaccines. These can be classified into distinct GMP manufacturing capabilities.

We operate four GMP-certified manufacturing facilities in Germany, where we manufacture mRNA therapeutics and engineered cell therapies both for our own pipeline and for external customers, including a state-of-the-art, multi-platform, GMP-certified manufacturing facility located in a life science industrial park in Marburg, Germany, which we acquired in October 2020 from Novartis to increase manufacturing capacity of our COVID-19 vaccine for commercial supply. We also operate a fifth facility in Germany where we manufacture custom peptides both to support our extensive immunomonitoring activities within our development programs and for third parties. Our subsidiary BioNTech Innovative Manufacturing Services GmbH, or BioNTech IMFS, has been manufacturing GMP-certified cellular products since 1999.

Our approach has been to proactively build capacity in anticipation of demand from both internal research and development from our collaborators. We have done so by continuing to make significant investments in our manufacturing infrastructure, including our capacity to manufacture mRNA, viral vectors, cellular products and peptides. We have also collaborated with Siemens AG to develop a process for automated, on-demand production of mRNA therapies. We believe that the development and optimization of our manufacturing processes in parallel to drug development is crucial to our success.

A. Manufacturing Operations

COVID-19 Vaccine. Our manufacturing site in Marburg was approved by the EMA for manufacturing of our COVID-19 drug product in March 2021. This approval makes it one of the largest mRNA manufacturing sites worldwide. In addition, we have two GMP facilities that currently produce our COVID-19 vaccine candidates for clinical trials. We have a broad network of sub-contractors established to provide drug substance, drug conjugate, drug product, and fill and finish services to enable production.

mRNA. We believe scaling up manufacturing for mRNA can best be executed as part of a proprietary manufacturing approach, rather than as part of an outsourcing strategy. We believe this approach allows us to maintain control of our proprietary processes and gives us the flexibility we need for scheduling batch production for our drug substances to match our development plans as they evolve. Our mRNA manufacturing is currently conducted at our in-house BioNTech IMFS facility, our BioNTech East Wing facility, and our Marburg facility. The East Wing facility is dedicated to iNeST (finished product) and bulk mRNA manufacturing. Our mRNA manufacturing process involves standardized production of all mRNA constructs and minimal restrictions in construct length. We have the capacity to undertake sterile filtration and final filling in up to 1,200 vials of various sizes in the East Wing and about 7,000 vials at IMFS. Batch sizes range from a few milligrams for individualized applications (*i.e.*, iNeST) to 10g for standard mRNA applications (*i.e.*, *FixVac*, intratumoral immunotherapies and infectious diseases), and up to 720g batches for COVID-19. Our manufacturing facility in Marburg is one of the largest mRNA vaccine manufacturing sites worldwide with an annual capacity of up to three billion doses of mRNA drug substance and we believe we are well positioned to supply the quantities required by global market demand.

To date, we have produced more than 2,000 batches of mRNA drug substance to support our clinical studies. We currently have infrastructure capable of producing about 100 batches of mRNA drug substance and formulated drug product per month with a turnaround time of about 30 to 40 days from sequence identification to released product. We believe we have the capacity to meet the supply needs of our current product candidates in clinical trials up to registration.

In recent years, we have successfully decreased the time required to deliver iNeST to patients. In 2014, it took us over three months to manually manufacture and deliver individualized immunotherapies to patients. Since December 2017, with the implementation of semiautomatic GMP manufacturing in collaboration with Siemens and other partners, we have been consistently manufacturing and delivering individualized immunotherapies in under six weeks. This advancement represents significant progress toward our target commercial manufacturing turnaround time of less than 28 days, and we were able to demonstrate less than 30 days in 2021. We plan to continue to develop additional process improvements, which we expect will further reduce our turnaround times as we progress through clinical development.

Cell Therapy Products. We have end-to-end capabilities and teams in Germany and the United States with over 20 years of experience in cell therapy manufacturing, quality control and release. Our cell therapy programs target novel and known tumor-specific antigens, including patient-specific mutant neoantigens. We also leverage our mRNA vaccine technology to further boost T cell activation, expansion, and persistence. Our state-of-the-art manufacturing processes of cellular products involve the isolation of primary human blood cells and subpopulations, such as, *e.g.*, CD3+ T-cells. Cell products are cultured, expanded and genetically modified (*e.g.*, CAR-T cells) in aseptic production processes in specialized cleanroom facilities. We also have the capability for in-house vector and mRNA production for the genetic modification of such innovative cell therapy products.

Peptides. Our custom peptide synthesis business has developed unique technologies to produce several million peptides over the past ten years to support our growing clinical pipeline. These include fast small-scale manufacturing of peptides for target and epitope discovery as well as for neoepitope characterization and production of high content arrays. It is important to synthesize highly purified peptides in order to avoid false positives in immunomonitoring in our mRNA immunotherapy trials. We also use these peptides as starting material in our engineered cell therapies. We have developed know-how to produce highly complex and purified peptide pools that consist of overlapping peptides spanning entire antigens or neoepitopes. We are currently building a new manufacturing plant of 7,500 square meters in Berlin to double

our manufacturing capacity, thus producing more than 100,000 purified peptides per year and more than one million unpurified peptides per year.

B. Manufacturing Facilities

Manufacturing sites in Germany

Marburg

Marburg is one of our fully owned, state-of-the-art manufacturing facilities for just-in-time delivery and scalable production. Our Marburg manufacturing facility was acquired from Novartis in 2020 for less than a hundred million euros and comprises eight large and small molecule production suites across more than 100,000 square feet. Within 6 months from acquisition, the facility was retrofitted to produce mRNA vaccines. It is now one of the largest mRNA vaccine manufacturing sites globally. As of 2022, the facility has the capacity to produce up to three billion doses of mRNA drug substance vaccine annually.

Marburg is our central hub for innovation and development of novel manufacturing solutions. It is a center of excellence, not only in terms of facilities and devices, but as a know-how hub with appropriate and forward-looking staff training. We have about 700 employees on site. To ensure production, we work in flexible/different shift models, e.g. 24/5.

In February 2023, we completed our first proprietary plasmid DNA manufacturing facility in Marburg. This aims to increase our flexibility and autonomy in manufacturing starting materials for our oncology and COVID-19 vaccine pipelines, as well as our independence for pandemic preparedness due to local production. We also expect that this manufacturing facility will facilitate faster production cycles and shorter delivery times for plasmid DNA for a number of clinical product candidates and commercial products.

Idar-Oberstein

BioNTech Innovative Manufacturing Services (IMFS): Our manufacturing operations for retroviral vectors, cell therapy products and mRNA are housed in our wholly owned subsidiary. Founded in 1997, BioNTech IMFS specializes in services for innovative therapeutic approaches. In 2009, BioNTech IMFS became our wholly owned subsidiary, giving us access to synergistic platforms and complementary expertise for development, testing and manufacturing services. BioNTech IMFS and its predecessors have had GMP-certified cell and gene therapy manufacturing capabilities since 1999, and obtained GMP manufacturing authorization for mRNA production in 2011. In 2017, BioNTech IMFS began automated manufacturing of the iNeST product candidate and entered into its first commercial supply contract for retroviral vectors. Located near Mainz, the BioNTech IMFS facility occupies over 30,000 square feet. Almost 500 staff members are employed at this facility, with collective expertise in molecular biology, cell biology and virology and a close working relationship with our R&D teams in Mainz. We consider BioNTech IMFS our powerhouse for early stage mRNA material.

Mainz

BioNTech iNeST Clinical Manufacturing (East Wing): We dedicate our GMP-certified manufacturing facility at our headquarters in Mainz, Germany to the production of iNeST immunotherapies and bulk mRNA manufacturing. In 2015, our wholly owned subsidiary, BioNTech RNA Pharmaceuticals GmbH, or BioNTech RNA, and Siemens announced a collaboration for developing an automated, paperless and digitalized production site for individualized mRNA. We obtained our GMP manufacturing authorization for iNeST production at our East Wing facility in June 2018 and manufactured our first drug product there the following month.

This facility contains approximately 17,000 square feet of laboratory and office space, including 4,300 square feet of GMP facilities. Almost 200 staff members are employed at this facility and operate it seven days per week. In its first year of operation, the facility manufactured and released more than 250 batches of mRNA and has manufactured and released more than 1,200 batches of mRNA since inception.

To perform our upstream process to feed into the iNeST downstream GMP manufacturing process, our headquarters also hold our core facility, which operates under GCP for labs and is currently under review to become CLIA-certified via CAP accreditation. Incoming patients' materials (blood and tumor samples) are received and analyzed, and characteristic mutations are identified before the mRNAs are constructed for each patient individually.

BioNTech Clinical Manufacturing: Our GMP-certified manufacturing facility in Kupferbergterrasse, Mainz is authorized to conduct secondary packing, labeling, storage and batch release of primary packed investigational medicinal products. This facility contains approximately 11,500 square feet of laboratory and office space, including 1,250 square feet of GMP facilities.

Berlin

JPT: JPT, our peptide manufacturing facility, was established in 2004 and became a wholly-owned subsidiary of BioNTech in 2008. JPT is located in Berlin and occupies over 16,000 square feet of clean rooms, laboratory and office space.

Global manufacturing sites

Outside of Europe, we have acquired a site in the United States for the clinical-scale manufacture of cell therapies and a site in Singapore for the manufacturing of clinical- and commercial-scale mRNA therapies.

Gaithersburg Clinical Manufacturing Facility.

We acquired our site in Gaithersburg, Maryland from Kite Pharma, Inc. in August 2021. The focus of this site is to supply cell therapy products for clinical trials in the United States and to support a potential commercial product launch upon approval. The facility also hosts our U.S.-based R&D team for cell therapy development.

Singapore Manufacturing Facility

In November 2022, our Singapore affiliate, BioNTech Pharmaceuticals Asia Pacific Pte. Ltd., entered into an agreement with Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd. to acquire one of its GMP-certified manufacturing facilities. The acquisition is part of our expansion strategy to strengthen our global footprint in Asia. Supported by the Singapore Economic Development Board (EDB), the facility will serve as our Regional Headquarters and become our first mRNA manufacturing facility in Singapore. The facility will create regional manufacturing capacities in support of our growing pipeline of mRNA-based vaccines and therapeutics across the Asia Pacific region at both commercial and clinical scales, with the potential to expand the production to other drug classes, such as cell therapies. The site will be a fully integrated mRNA manufacturing facility bringing mRNA production capabilities across drug substance and drug product, with an expected annual production capacity of up to several hundred million doses of mRNA-based vaccines after a full build-out.

The *BioNTainer*: a platform for localized and sustainable mRNA production

The *BioNTainer* is an example of our innovative approach to establishing scalable vaccine production by developing and delivering turnkey mRNA manufacturing facilities based on a container solution. It was developed to ensure sustainable, equitable access to our programs, particularly in low-income countries and regions with limited infrastructure. Introduced in February 2022, the *BioNTainer* allows scalable vaccine production by developing and delivering turnkey mRNA manufacturing facilities based on a container solution that works as a “Plug & Play” approach with modular design, standardized equipment, and software components. Each *BioNTainer* is a clean room, which we equip with state-of-the-art manufacturing solutions, consisting of one drug substance and one formulation module. Each module is built of six to eight ISO-sized containers. A *BioNTainer* can be equipped to manufacture a range of mRNA-based vaccines targeted to regional needs: for example, our COVID-19 vaccine and our investigational malaria and tuberculosis vaccines, if they are successfully developed, approved, and authorized by regulatory authorities and in line with regional demand. Each *BioNTainer* is intended to become a node in a decentralized and robust end-to-end manufacturing network, aiming to offer greater independence and faster regional vaccine supply. We will initially staff and operate the facilities to enable the safe and rapid initiation of the production of mRNA-based vaccine doses under stringent good manufacturing processes, in order to prepare for the transfer of know-how to local partners to facilitate operation. We believe this solution is an important step towards improving global vaccine supply.

In addition to our *BioNTainer* facility in Kigali, Rwanda, we announced in December 2023 that we intend to set up and operate a clinical-scale mRNA manufacturing facility with *BioNTainer* units in Melbourne in the State of Victoria, Australia. The site is intended to support R&D and clinical-scale manufacturing of investigational mRNA-based medicines from the local ecosystem as well as from other third parties globally.

Kigali Manufacturing Facility

In December 2022, six ISO-sized shipping containers for the first *BioNTainer* finished construction in Europe and underwent quality checks by our experts. The first shipment of *BioNTainer* units to Kigali, Rwanda arrived in March 2023. The Kigali facility is planned to initially house two sets of *BioNTainer* units for bulk production of mRNA vaccines and is intended to be part of a robust end-to-end manufacturing network in Africa for mRNA-based medicines. In December 2023, we reached the next milestone in the establishment of mRNA vaccine manufacturing capacities in Africa with the inauguration of our site in Kigali, Rwanda. The inauguration took place on the occasion of the set-up of the first *BioNTainer*.

The Rwandan facility is intended to be a commercial manufacturing and production facility. Once fully operational, the facility's capacity would depend on the product and its dosage. For example, if used to produce the Pfizer-BioNTech COVID-19 vaccine, the first set of *BioNTainer* units could produce an estimated initial annual capacity of up to 50 million doses. The facility is expected to employ approximately 100 people once operational, with roles across a range of disciplines. BioNTech plans to complete all buildings at the Kigali site and start local training of specialized personnel in the facility in 2024, with test mRNA production for process validation to be initiated in 2025.

In line with the continent's and partner countries' needs, BioNTech is committed to establishing additional manufacturing facilities in Africa upon the successful validation of the facility in Kigali.

C. Other Certifications

BioNTech Diagnostics has a quality management system that is certified according to ISO 13485:2016 and JPT maintains a ISO 9001:2015 certified Quality Management System to allow production of European CE marked companion diagnostics.

D. Quality Assurance

We have implemented and maintain several Quality Assurance systems. BioNTech IMFS, BioNTech Clinical Manufacturing and BioNTech iNeST Clinical Manufacturing have implemented GMP-certified quality assurance systems. BioNTech Diagnostics has a quality management system that is certified according to ISO 13485:2016 and JPT maintains a ISO 9001:2015 certified Quality Management System.

IX. Third-Party Collaborations

We have forged productive collaborations with pharmaceutical companies and academic research institutions with area expertise and resources in an effort to advance and accelerate our discovery and development programs in oncology, and also to leverage our drug classes into additional disease indications while minimizing our incremental costs.

Our collaborations include, without limitation:

- Autolus for certain binders and the right to utilize its manufacturing capacity;
- Biotheus for certain antibodies;
- DualityBio for the research and development of certain antibody drug conjugates;
- Fosun Pharma for our COVID-19 vaccine program;
- Genentech for our iNeST platform in our mRNA drug class;
- Genmab for our next-generation checkpoint immunomodulator platform in our protein-based therapeutics drug class;
- InstaDeep, now our wholly-owned subsidiary, for AI and ML;
- OncoC4 for the research and development of certain monoclonal anti-CTLA4 antibodies; and
- Pfizer for our COVID-19, influenza and joint COVID-19/influenza vaccine programs, which leverage technology from our infectious disease mRNA-based platform.

We either wholly own or retain significant rights to all of our clinical stage programs, either in the form of a global share of profit and co-commercialization rights with our collaborators in certain markets or significant royalties and

milestones. We plan to continue to identify potential collaborators who can contribute meaningful resources and insights to our programs and allow us to more rapidly expand our impact to broader patient populations.

A. Autolus Collaboration

License and Option Agreement

On February 6, 2024 (with effect as of February 13, 2024), we entered into a License and Option Agreement, or the Autolus License Agreement, with Autolus Therapeutics plc's wholly-owned subsidiaries Autolus Limited and Autolus Holdings (UK) Limited, which collectively we refer to as Autolus, pursuant to which Autolus granted to us an exclusive, worldwide, sublicensable license, which we refer to as the Autolus License, to certain binders and to exploit products that express in vivo such binders, which we refer to as the Binder Licensed Products. Autolus also granted to us several time-limited options, or the Autolus Options, to acquire additional rights to specified clinical-stage product candidates, binders and technologies of Autolus, described in more detail below.

In the event that all Autolus Options are fully exercised, Autolus would be eligible to receive maximum aggregate payments of up to \$582 million pursuant to the Autolus License Agreement. This maximum amount includes upfront payments, the potential milestone payments for the Binder Licensed Products described below, all option exercise fees and potential milestone payments for licenses to optioned products and technologies, and additional payments that we may pay to Autolus for an increased revenue interest with respect to Autolus's product candidate, obe-cel, as described below.

In consideration for the Autolus License and the Autolus Options, we made an initial payment to Autolus of \$10 million. Autolus is eligible to receive milestone payments of up to \$32 million in the aggregate upon the achievement of specified clinical development and regulatory milestones for each Binder Licensed Product that achieves such milestones. Autolus is also eligible to receive a low single-digit royalty on net sales of Binder Licensed Products, subject to customary reductions, which reductions are subject to specified limits. The royalty will be increased if we, our affiliates or our sublicensees commercialize a Binder Licensed Product in an indication and country in which Autolus or its affiliates or licensees also commercialize a product containing the same binders. Under the License Agreement, we are solely responsible for, and have sole decision-making authority with respect to, at our own expense, the exploitation of Binder Licensed Products.

Under the terms of the License Agreement, Autolus has agreed to grant us the following time-limited Autolus Options:

- an option to obtain exclusive rights to co-fund development costs of Autolus's development-stage programs AUTO1/22 and AUTO6NG, in return for agreed upon economic terms, including an option exercise fee, milestone payments and a profit-sharing arrangement for each such product candidate, with additional options to co-promote or co-commercialize such product candidate;
- an option to obtain an exclusive worldwide license to exploit products that express certain additional binders in vivo or, with respect to certain binders, in an antibody drug conjugate, or the Binder Option;
- an option to obtain a co-exclusive worldwide license to exploit products that express in vivo Autolus's modules for activity enhancement, with a non-exclusive right, in certain agreed instances, to exploit products that include Autolus's modules for activity enhancement but do not express in vivo such modules, or the Activity Enhancement Option; and
- an option to obtain a non-exclusive worldwide license to exploit products that contain Autolus's safety switches or the Safety Switch Option, and, together with the Binder Option and the Activity Enhancement Option, the Technology Options.

The option exercise fee for each Technology Option is a low seven-digit amount. Each of the Activity Enhancement Option and the Safety Switch Option must be exercised with respect to a given biological target or combination of targets. There is a cap on the total option exercise fee if multiple Technology Options are exercised with respect to a given target.

There is also a cap on milestone payments across all agreements entered into as the result of our exercising one or more of the Technology Options and a cap on royalties payable on any given product for which multiple Technology Options are exercised.

Under the Autolus License Agreement, we have also agreed to financially support the expansion of the clinical development program for, and planned commercialization of, Autolus's lead product candidate obecabtagene autoleucel, known as obe-cel. In exchange for Autolus's grant of rights to future revenues from the sales of obe-cel products, we made

an upfront payment to Autolus of \$40 million. Autolus will pay us a low single-digit percentage of annual net sales of obe-cel products, which may be increased up to a mid-single digit percentage in exchange for milestone payments of up to \$100 million in the aggregate on achievement of certain regulatory events for specific new indications.

Under the terms of the Autolus License Agreement, Autolus has agreed to grant to us the option to negotiate a joint manufacturing and commercial services agreement pursuant to which the parties may access and leverage each other's manufacturing and commercial capabilities, in addition to Autolus's commercial site network and infrastructure, with respect to certain of each parties' CAR-T products, including our product candidate, BNT211, or the Autolus Manufacturing and Commercial Agreement.

Unless earlier terminated, the Autolus License Agreement will continue for so long as royalties are payable in respect of Binder Licensed Products and the revenue interest is payable in respect of obe-cel products. Subject to a cure period, either party may terminate the Autolus License Agreement in the event of the other party's uncured material breach or the insolvency of the other party. We may terminate the Autolus License Agreement, in whole or in part, for any or no reason upon a specified period of prior written notice to Autolus.

Securities Purchase Agreement, Registration Rights Agreement and Letter Agreement

Concurrently with the execution of the Autolus License Agreement, we entered into a Securities Purchase Agreement, or the Autolus Purchase Agreement, pursuant to which we purchased from Autolus American Depositary Shares, or the Autolus ADSs, each representing one ordinary share of Autolus, or the Autolus Ordinary Shares, in a private placement transaction, or the Autolus Private Placement.

At the initial closing on February 13, 2024, or the Initial Closing, Autolus issued 33,333,333 Autolus ADSs, or the Initial ADSs, to us for a total aggregate purchase price of \$200 million. In the event that we and Autolus enter into an Autolus Manufacturing and Commercial Agreement within 18 months of the Initial Closing, we have agreed to purchase additional Autolus ADSs, or the Subsequent ADSs and, together with the Initial ADSs, the Private Placement ADSs, not to exceed 15,000,000 Autolus ADSs, for an aggregate purchase price of up to \$20 million. The total number of Subsequent ADSs that may be issued is subject to additional limitations and restrictions. The Autolus Purchase Agreement contains customary representations, warranties, and covenants.

Concurrently with entry into the Purchase Agreement, we entered into a letter agreement, or the Autolus Letter Agreement, providing us with certain additional rights and subjecting our investment in Autolus to certain restrictions. Pursuant to the Autolus Letter Agreement, we received the right to nominate a director to Autolus's board of directors. If we acquire beneficial ownership of at least 30% of the issued and outstanding Autolus Ordinary Shares within five years of the date of the Autolus Letter Agreement, we will have the right to designate an additional director, who shall be independent. Our director nomination rights under the Autolus Letter Agreement shall automatically terminate upon our ownership of Autolus Ordinary Shares dropping below certain specified percentages. Additionally, pursuant to the Autolus Letter Agreement, we have the right to purchase equity securities sold by Autolus in bona fide financing transactions in amounts that are based on our maintaining specified ownership thresholds following such financing transactions. Pursuant to the Autolus Letter Agreement, subject to specified exceptions, we may not sell the Private Placement ADSs without Autolus's approval for a period of six months following the applicable closing date for such Autolus ADSs. The Autolus Letter Agreement terminates upon the earlier of (a) the later of (i) three years from its signing date and (ii) such time as no securities of Autolus are held by us or our affiliates and (b) the consummation of a change of control transaction involving Autolus.

We and Autolus also entered into a registration rights agreement, pursuant to which Autolus has agreed to file a registration statement with the Securities and Exchange Commission to register the resale of the Private Placement ADSs.

B. Biotheus Collaboration

On October 26, 2023 (with effect as of December 2, 2023), we entered into a Collaboration, Option and License Agreement, or the Biotheus Collaboration Agreement, with Biotheus for the global development, manufacturing and commercialization of PM8002, a clinical stage bispecific antibody, and certain derivatives, directed to PDL-1 and VEGF, or the PM8002 Licensed Products. Biotheus retained the right to develop and commercialize PM8002 Licensed Products in mainland China, Hong Kong, Macau and the region of Taiwan, or the Biotheus Retained Territory, and we were granted the right to develop and commercialize such products outside the Biotheus Retained Territory, which we refer to as the territory.

Biotheus granted us an exclusive, royalty-bearing, sublicensable license to research, develop, manufacture and commercialize PM8002 Licensed Products, in the territory. Biotheus also granted us exclusive options to obtain exclusive,

royalty-bearing, sublicensable licenses to exploit (i) PM8003, a trispesific antibody, and certain derivatives, directed to PDL1, VEGF and TGF β , or the PM8003 Licensed Products, in the territory and (ii) any preclinical stage multispecific antibodies proprietary to Biotheus and directed to PDL1, VEGF and at least one other target, or the Preclinical Multispecific Licensed Products in the territory.

We granted to Biotheus an exclusive option to obtain an exclusive, royalty-bearing, sublicensable license to exploit multispecific antibodies that are variants of PM8002 Licensed Products directed to PDL1, VEGF and at least one other target, or the BioNTech Multispecific Antibodies in the Biotheus Retained Territory.

In consideration for the rights granted to us, Biotheus received an upfront payment of \$55 million in cash, and is eligible to receive payments for development, regulatory and sales milestones potentially totaling over \$1 billion, as well as tiered low double-digit royalties on potential future product sales.

The Biotheus Collaboration Agreement continues on a licensed product-by-licensed product basis until the last to expire payment obligation with respect to such licensed product on a country-by-country basis in the territory. Upon the expiration of the royalty term for a licensed product in a given country in the territory, the exclusive license granted to us will become a perpetual, irrevocable, exclusive, fully paid-up, and royalty-free license with respect to such licensed product in such country.

In addition to termination rights granted to each party in the case of the other party's uncured material breach or insolvency, we may terminate the Biotheus Collaboration Agreement in its entirety or on a licensed product-by-licensed product basis for convenience with prior written notice.

C. DualityBio Global Strategic Partnership

In 2023, we entered into three License and Collaboration Agreements with DualityBio, which we refer to as the DualityBio Agreements. Each of the DualityBio Agreements relates to specific ADC assets. The first agreement, the HER2 Agreement, relates to the ADC asset targeting HER2 and was entered into on March 16, 2023. The second agreement, the B7H3 Agreement, relates to the ADC asset targeting B7H3 and was entered into on March 31, 2023. The third agreement, the TROP2 Agreement, relates to the ADC asset targeting TROP2 and was entered into on August 4, 2023.

Each of the three DualityBio Agreements relates to a license granted to us with respect to certain patents and know-how owned or otherwise controlled by DualityBio and our collaboration with DualityBio in the research and development of ADC therapeutics.

In each of the DualityBio Agreements, DualityBio granted us the exclusive, royalty-bearing and sublicensable right to exploit certain patents and know-how, which we refer to as the DualityBio IP, for the research, development, manufacture and commercialization of the respective ADC compound and pharmaceutical products comprising such compound, which we refer to as the DualityBio Products, in any field in the territory, which is all countries of the world except for mainland China, Hong Kong and Macau, which we refer to as the DualityBio Retained Territory. We were also granted the sole right to exploit the DualityBio IP to develop and manufacture the DualityBio Products in the DualityBio Retained Territory solely for the purpose of developing, manufacturing and commercializing the DualityBio Products in the territory.

Each party has final decision-making authority and is generally responsible for clinical trial supply costs and regulatory activities and costs with respect to their respective territory.

We are responsible for the commercialization of any DualityBio Products in the territory.

The B7H3 Agreement also grants DualityBio the option to share the development and commercialization costs and the profits and losses from the exploitation of the first original DualityBio Product in the United States. Under the B7H3 Agreement, we have further granted to DualityBio the option to assume a percentage of the total sales force of the first original DualityBio Product in the United States.

In partial consideration of DualityBio's granting of the licenses and rights to us under the DualityBio Agreements, we have made upfront payments to DualityBio in an aggregate amount of \$220 million. In addition, we agreed to make potential payments upon the achievement of specified development, regulatory and commercial milestones. Such milestone payments could amount up to \$2.6 billion in the aggregate (the TROP2 Agreement also provides for additional sales milestone payments in the event DualityBio works on, and we exercise, the option regarding the next-generation product). We further agreed to between single-digit to double-digit tiered royalties on net sales of all DualityBio Products, which also differ between the DualityBio Agreements. Royalties are subject to stacking provisions and will be reduced in case of respective biosimilar products entering the market. Furthermore, we agreed to reimburse DualityBio for certain development costs.

The DualityBio Agreements end on a country-by-country and DualityBio Product-by-DualityBio Product basis upon expiration of the respective last DualityBio royalty term for a DualityBio Product in that country. Thereafter, the licenses granted to us with respect to such product in such country will convert into a perpetual, exclusive, fully paid-up and royalty-free license. In addition to termination rights granted to each party in the case of the other party's uncured material breach or insolvency, we may terminate each DualityBio Agreement, in whole or in part, for convenience upon prior written notice.

D. Fosun COVID-19 Vaccine Collaboration

On March 13, 2020, we entered into a Development and License Agreement with Shanghai Fosun Pharmaceutical Industrial Development, Co., Ltd, or Fosun Pharma, for the development and commercialization in mainland China, Hong Kong special administrative region, or SAR, Macau SAR and in the region of Taiwan, or collectively the Fosun Collaboration Territory, of immunogenic compositions generated by BioNTech and comprising uridine RNA, modified RNA and/or replicon technology for prophylaxis against SARS-CoV-2 in humans. We refer to this agreement as the Fosun Agreement.

The details of the development activities to be undertaken by Fosun Pharma are to be set forth in a development plan that is being overseen by a Joint Steering Committee. Fosun Pharma's development activities are to be undertaken at its own cost and expense. Fosun Pharma has the sole responsibility to prepare, obtain and maintain regulatory approvals for the vaccine candidates in the Fosun Territory. We agreed to give Fosun Pharma reasonable assistance with the regulatory aspects of these activities.

Fosun Pharma has the sole responsibility, authority and control of the commercialization of a vaccine candidate in the Fosun Collaboration Territory, but must use commercially reasonable efforts to do so in accordance with an agreed commercialization plan, including by launching a vaccine product in the Fosun Collaboration Territory within three months after receiving marketing approval for it, provided sufficient quantities of the vaccine have been delivered.

We retain the sole right to manufacture (or have manufactured) and supply any vaccine candidates and products for development purposes and commercial sale in the Fosun Territory. We agreed to manufacture and supply all quantities of vaccine from a GMP-certified RNA manufacturing facility. As compensation for supply of the vaccine Fosun Pharma will reimburse us our manufacturing costs plus an administrative fee that is between 10 and 19 percent.

Under the Fosun Agreement, we granted Fosun Pharma an exclusive license under certain of our owned or in-licensed intellectual property, including our patents relating to replicons, uridine RNA and modified RNA and other mRNA technology or a vaccine to use, develop, commercialize and otherwise exploit the vaccine candidates in the Fosun Territory. In the event of any failure of the development of a vaccine, we agreed to grant Fosun Pharma a right of first negotiation on a separate competent vaccine for the prophylaxis of COVID-19 in the Fosun Collaboration Territory.

In consideration of the rights granted to Fosun Pharma under the Fosun Agreement, Fosun Pharma subscribed for \$50 million of our ordinary shares under a separate investment agreement. In addition, under the Fosun Agreement, Fosun Pharma made an upfront payment of \$1 million and agreed to potential payments of up to \$14 million upon the achievement of specified development and regulatory milestones and up to \$70 million upon the achievement of specified sales milestones. Fosun Pharma further agreed to pay us a royalty rate that is between 30 and 50 percent of its profits on net sales of a vaccine product, if approved, for a period of 15 years from launch of that vaccine in the Fosun Territory.

The Fosun Agreement ends upon expiration of the royalty term. Fosun Pharma may elect to continue to pay royalties and extend the agreement and its rights thereunder. In addition to termination rights granted to each party in the case of the other party's uncured material breach or insolvency, Fosun Pharma may terminate the agreement, in whole, for convenience and with or without reason at any time upon 180 days' prior written notice. If the agreement is terminated by Fosun Pharma for cause, the licenses to Fosun Pharma survive, we will manufacture and deliver the vaccine candidate or product for one year and we will grant a non-exclusive license to a reasonably acceptable contract manufacturing organization for manufacturing of the vaccine candidate or product thereafter for development and commercialization by Fosun Pharma in the Fosun Collaboration Territory.

During the term of the Fosun Agreement, we have committed not to license to any other third party in the Fosun Collaboration Territory the intellectual property licensed to Fosun for the same purpose and not to develop or commercialize the same vaccine candidate or any coronavirus vaccine in the Fosun Collaboration Territory.

E. Genentech iNeST Collaboration

Collaboration Agreement

On September 20, 2016, we and BioNTech RNA entered into a Collaboration Agreement with Genentech and F. Hoffman-La Roche Ltd, which, as amended on June 1, 2018 and December 6, 2019, we refer to as the Genentech Collaboration Agreement, to jointly research, develop, manufacture and commercialize certain pharmaceutical products that comprise neoepitope RNAs, or the Genentech Collaboration Products, which include our iNeST development candidates, for any use worldwide. Under the Genentech Collaboration Agreement, we and Genentech agreed to perform joint research under a research plan to further improve our technology platform for the manufacturing of Genentech Collaboration Products. Under the terms of the Genentech Collaboration Agreement, Genentech paid us \$310 million in upfront and near-term milestone payments.

We and Genentech must use commercially reasonable efforts to jointly develop one or more Genentech Collaboration Products in accordance with an agreed global development plan, with the costs of such development to be shared equally. We will continue certain clinical studies that were initiated prior to the execution of the Genentech Collaboration Agreement at our sole expense, and any future material changes in the operation of such clinical studies require Genentech's approval. Genentech may access and use any data generated in these ongoing clinical studies.

In addition to the clinical studies included in the global development plan, we may propose certain additional clinical studies for indications not included in the global development plan, and if the joint development committee formed by the parties does not elect to include the proposed studies in the global development plan, then we may conduct the study at our sole expense under certain conditions, and subject to certain restrictions. Genentech has the option to select any candidate in such studies for potential further joint development and/or commercialization by Genentech as a Genentech Collaboration Product. In the case that Genentech wishes to pursue the clinical development of a Genentech Collaboration Product in an indication that we are not interested in pursuing, then under certain conditions, we may opt out of the co-funding of such development and Genentech may continue do so at its own costs, except that we are obligated to repay Genentech's development costs in the event that such product subsequently receives regulatory approval.

Genentech has the sole right to commercialize the Genentech Collaboration Products on a worldwide basis, with all profits and losses from such commercialization to be split equally with us. If we exercise our right to opt out of sharing equally in future development costs for any Genentech Collaboration Products, then we will no longer split all such profits and losses for such Genentech Collaboration Products equally with Genentech and will instead receive a royalty on annual worldwide net sales of such Genentech Collaboration Products that are covered by a valid claim included in certain of our patents and certain joint patents that arise out of the collaboration. Furthermore, for certain Genentech Collaboration Products for which we share co-promotion rights with Genentech, we have the option to assume a percentage to be determined of the total sales force in the United States, and certain other countries, including Germany and other major European markets. In addition, under certain regulatory and other circumstances, we have the right to independently commercialize Genentech Collaboration Products in indications that the joint development committee declines to pursue and that Genentech does not subsequently elect to commercialize, provided that we market such Genentech Collaboration Products under a separate brand and trademark that is approved by the joint commercialization committee established by the parties as not confusingly similar to the Genentech Collaboration Products being commercialized by Genentech. Our ability to research, develop, co-promote and/or independently commercialize Genentech Collaboration Products may be terminated or limited in the event we undergo a change of control.

We granted to Genentech an exclusive license under certain of our intellectual property, and our interest in any jointly-owned intellectual property developed under this agreement, to research, develop, make, sell and import any pharmaceutical products that comprise neoepitope RNA. Genentech granted to us an exclusive, non-transferable, sublicensable licenses under certain Genentech intellectual property, our intellectual property exclusively licensed to Genentech, and their interest in any jointly-owned intellectual property developed under this agreement for the performance of our ongoing clinical studies and the exercise of our rights and obligations under the Genentech Collaboration Agreement.

Until the first marketing approval for a Genentech Collaboration Product, we have granted Genentech the first right to negotiate an exclusive license to develop, manufacture and commercialize combination therapies involving pharmaceutical products based on neoepitope RNA and pharmaceutical products based on non-neoepitope RNA for the treatment of cancer in humans.

The Genentech Collaboration Agreement will remain in effect so as long as Genentech Collaboration Products are in development or commercialization, or until the date of the expiration of the last royalty term if BioNTech has exercised its option to opt-out of joint development of Genentech Collaboration Products. If the agreement expires, the licenses granted

to Genentech become fully-paid up, royalty-free and irrevocable. Genentech may terminate the Collaboration Agreement if we fail to achieve certain milestone targets or at any time for convenience with or without reason upon 60 days' prior written notice. In the event of any such termination, all rights to the development and commercialization of Genentech Collaboration Products developed under the collaboration would revert to us and Genentech would grant us licenses under its intellectual property to further develop and commercialize Genentech Collaboration Products. We would be required to pay certain royalties to Genentech for such license(s). In addition, either party may terminate the agreement upon the other party's uncured material breach or insolvency.

Manufacturing Development and Supply Agreement

Concurrent with the Genentech Collaboration Agreement, we entered into a Manufacturing Development and Supply Agreement with Genentech and F. Hoffman-La Roche Ltd, or the Genentech Manufacturing Agreement, which governs the manufacturing, related manufacturing development activities and supply of Genentech Collaboration Products. Pursuant to the Genentech Manufacturing Agreement, we are responsible for clinical manufacturing and supply, for developing and implementing manufacturing processes (including pursuant to specified target turnaround times), and for constructing, commissioning, qualifying and obtaining permits for the clinical facilities. We are permitted to subcontract certain steps in the clinical manufacturing process to our affiliate, BioNTech IMFS.

In addition, we are responsible for developing the commercial manufacturing process, which requires more stringent turnaround times than the clinical manufacturing process. Genentech will generally be responsible for conducting commercial manufacturing. We are obligated to use commercially reasonable efforts to achieve certain predetermined clinical manufacturing capacity commitments.

Under the Genentech Manufacturing Agreement, we and Genentech will jointly develop a manufacturing network plan detailing the location, capacity, scale-out, associated timing and other appropriate details of the commercial manufacturing facilities. We may participate in commercial manufacturing through our right to include as part of the commercial manufacturing network one of our own facilities in the European Union or the United States and one of our own facilities in another region to be agreed upon with Genentech (provided that in each region our facility is not the first facility to be included in the commercial manufacturing network).

F. Genmab Next-generation Immunomodulator Collaboration

On May 19, 2015, we entered into a License and Collaboration Agreement with Genmab (together with all amendments and side letters thereto, collectively referred to as the Genmab Agreement) to jointly research, develop and commercialize polypeptide-based bispecific antibodies against certain target combinations for the treatment of cancer worldwide, or the Genmab Agreement Field, using certain Genmab technology. In connection with our entry into the Genmab Agreement, Genmab paid us an upfront fee of \$10 million.

Under the Genmab Agreement, we and Genmab must use commercially reasonable efforts to research and develop clinical candidates, including our next-generation checkpoint immunomodulators, with costs split equally during the research and evaluation phase. Our joint activities in this phase are governed by a research plan, which is subject to annual review and updates, and which specifies the clinical candidates to be developed. This research and evaluation phase expired on September 18, 2022.

We and Genmab must use commercially reasonable efforts to develop candidates selected by the joint research committee, or the Genmab Collaboration Products, through preclinical and clinical development. In addition, the joint research committee may select an additional candidate, or the Genmab Back-up Candidate, as a back-up for each Genmab Collaboration Product and may decide at any time to replace the Genmab Collaboration Product with its Genmab Back-up Candidate. The preclinical and clinical development of the Genmab Collaboration Products would be performed pursuant to a development plan to be agreed upon by us and Genmab, with costs to be split equally. The joint steering committee may designate a third party as a manufacturer of a Genmab Collaboration Product or of any of its components.

We and Genmab must use commercially reasonable efforts to jointly commercialize all Genmab Collaboration Products and share equally all expenses and profits arising from such commercialization. We and Genmab, on a product-by-product basis and at least 12 months prior to the anticipated start of a pivotal clinical trial for a Genmab Collaboration Product, will jointly designate between the two of us a lead party responsible for establishing the distribution and marketing operations in each geographical region. Each party would be entitled to equally co-promote the products pursuant to a separately negotiated global commercialization agreement that the parties agree to negotiate.

Unless otherwise agreed by the joint steering committee established under the agreement, Genmab is responsible for all regulatory actions and shall own all regulatory approvals obtained for the Genmab Collaboration Products. Genmab is obligated to provide regular updates to us on regulatory activities.

Each party grants to the other party a worldwide, co-exclusive, sublicensable, royalty-free license under certain of such first party's intellectual property, including certain patents and know-how, to perform the research under this agreement and to research, develop, make, import, use and sell Genmab Collaboration Products in the Genmab Agreement Field pursuant to the terms of the Genmab Agreement. These licenses shall continue on a country-by-country and product-by-product basis for as long as development or commercialization activities are contemplated under the Genmab Agreement.

During the research and evaluation phase prior to the selection of a Genmab Collaboration Product, neither we nor Genmab may engage in any research and development activity in the Genmab Agreement Field relating to the development of any bispecific antibody which targets any combination that is the subject of our joint research plan. During the preclinical and clinical development phase for any Genmab Collaboration Product, engagement in research and development activities in the Genmab Agreement Field unilaterally by a party relating to a Genmab Collaboration Product or its Genmab Back-up Candidate or any bispecific antibody which targets the same target combination for which such Genmab Collaboration Product or Genmab Back-up Candidate has been developed would require the other party's prior written consent.

Each party has the right to discontinue its participation in the further development and commercialization of a Genmab Collaboration Product at two points: (i) when an IND submission package has been agreed upon by the parties and (ii) when the draft clinical trial report from the first Phase 1/2 clinical trial becomes available. The party that wishes to opt out of such further development and commercialization may choose to permit the other party to continue the development and commercialization of the Genmab Collaboration Product or divest its interest in such Genmab Collaboration Product. If the opt-out party permits continued development and commercialization, the other party may elect to pursue development and commercialization of such Genmab Collaboration Product alone as a Unilateral Product, at its sole cost and subject to pre-defined milestone and royalty payments and certain additional pre-defined terms. If the other party wishes to not pursue such continued development and commercialization on such pre-defined payment and additional terms, then the parties will jointly divest their interest in such Genmab Collaboration Product to a third party, and if such divestiture fails, the parties will cease all development and commercialization of such Genmab Collaboration Product. Alternatively, if the opt-out party seeks to unilaterally divest its interest in the applicable Genmab Collaboration Product, the other party has the right of first exclusive negotiation to obtain exclusive, worldwide rights to develop and commercialize such Genmab Collaboration Product. If such unilateral divestiture fails after the other party's exercise of its right of first exclusive negotiation, the opt-out party may either continue development and commercialization of such Genmab Collaboration Product or offer the other party to continue such development and commercialization on such pre-defined payment and additional terms as set forth above.

The Genmab Agreement will remain in effect until the later of (i) the expiration of the last-to-expire royalty term for any Unilateral Product or (ii) the time when no Genmab Collaboration Products are being developed or commercialized under this agreement. Either party may terminate the agreement in its entirety or on a product-by-product basis with immediate effect upon the other party's uncured material breach or insolvency.

On August 5, 2022, we and Genmab expanded our global strategic collaboration to develop and commercialize novel immunotherapies for the treatment of cancer patients. Under this expansion, we and Genmab will jointly work to research, develop and commercialize novel monospecific antibody candidates for various cancer indications.

Under the expanded collaboration, the companies will jointly develop and commercialize, subject to regulatory approval, monospecific antibodies leveraging Genmab's proprietary HexaBody technology platform. The first monospecific antibody candidate, GEN1053/BNT313, entered clinical trials in late 2022. GEN1053/BNT313 is a CD27 antibody based on the HexaBody technology, specifically engineered to form an antibody hexamer (a formation of six antibodies) upon binding its target on the cell membrane of the T cells. Under the terms of the agreement, the companies will equally share the development costs and potential future profit deriving from GEN1053/BNT313.

G. InstaDeep Acquisition

On January 10, 2023, we entered into a share purchase agreement, or SPA, with the shareholders of InstaDeep Ltd., or InstaDeep, a leading global technology company in the field of artificial intelligence, or AI, and machine learning, or ML, under which we agreed to acquire 100% of the remaining shares in InstaDeep, excluding the shares already owned by us. The SPA was amended on July 31, 2023 to deal with certain matters arising after its execution.

Following the satisfaction of several customary closing conditions and regulatory approvals as defined in the SPA, the acquisition closed on July 31, 2023.

The total consideration to acquire the remaining InstaDeep shares, excluding the shares already owned by BioNTech, amounts to approximately €500 million in cash, BioNTech shares, and performance-based future milestone payments.

InstaDeep now operates as a UK-based global subsidiary and will continue to provide its services to clients around the world in diverse industries, including in the Technology, Transport & Logistics, Industrial and Financial Services sectors. Additionally, the acquisition is enabling the creation of a fully integrated, enterprise-wide capability that leverages AI and ML technologies across our therapeutic platforms and operations.

H. OncoC4 Collaboration

On March 17, 2023, we and OncoC4 entered into a License and Collaboration Agreement, or the OncoC4 Agreement, for the license, development and commercialization of ONC-392 and all other monoclonal anti-CTLA4 antibodies owned or controlled by OncoC4 (referred to as OncoC4 Licensed Compounds) as of the execution date, including development of combinations of such antibody with other products, for use in humans or animals, or the OncoC4 Field.

OncoC4 granted us an exclusive license under ONC-392 and OncoC4's interest in joint intellectual property to exploit OncoC4 Licensed Compounds and any pharmaceutical or biologic product containing OncoC4 Licensed Compound (referred to as OncoC4 Licensed Products) in the OncoC4 Field in the entire world, which we refer to as the OncoC4 Territory. Furthermore, OncoC4 granted us an exclusive option to license AI-061, which is a biopharmaceutical composition containing as its sole active ingredients both ONC-392 and an anti-PD-1 antibody. OncoC4 retains all rights to the anti-PD-1 antibody outside of the combination with ONC-392.

We agreed to collaborate on research, development, and commercialization of ONC-392 in the OncoC4 Territory and to use commercially reasonable efforts to conduct development activities of OncoC4 Licensed Compounds and OncoC4 Licensed Products either as a monotherapy or in combination with an anti-PD-(L)1 antibody and/or standard of care product (which we refer to collectively as the Mono/PD-1/SOC Combinations) in accordance with a joint clinical development plan which is governed by a joint steering committee. All costs associated with the joint development responsibilities are shared equally between us and OncoC4.

We are solely responsible for all development activities for the OncoC4 Licensed Compounds and OncoC4 Licensed Products in any other form or combination other than the Mono/PD-1/SOC Combinations (we refer to such other combinations as OncoC4 Other Combinations) at our own expense and in accordance with a research and development plan prepared by us and shared with OncoC4 through the joint steering committee. We agreed to use commercially reasonable efforts to develop an OncoC4 Licensed Product in at least one indication for an OncoC4 Other Combination. We agreed to first offer OncoC4 the opportunity to co-fund any development of a PD-1 Combination prior to pursuing such development independently or with a third party.

We agreed to be solely responsible, at our expense, for commercialization of OncoC4 Licensed Products worldwide and to use commercially reasonable efforts to commercialize OncoC4 Licensed Products for each approved indication in certain major markets.

In consideration for the rights granted to us by OncoC4, we made an upfront payment of \$200 million, with a portion of the upfront payment to be used to fund OncoC4's share of the joint research and development costs related to ONC-392, and agreed to make potential payments upon the achievement of specified development and regulatory milestones and upon the achievement of specified sales milestones. We have further agreed to pay OncoC4 double digit, tiered royalties on annual net sales of OncoC4 Licensed Products during a certain royalty term starting from launch of product.

The OncoC4 Agreement shall continue until the last-to-expire royalty term in all countries in the OncoC4 Territory for all OncoC4 Licensed Products. Upon the expiration of the royalty term for an OncoC4 Licensed Product in a given country in the OncoC4 Territory, the exclusive license granted to us will become a perpetual, irrevocable, non-exclusive, fully paid-up, and royalty-free license with respect to such OncoC4 Licensed Product in such country. In addition to termination rights granted to each party in the case of the other party's uncured material breach or insolvency, we have the right to terminate the OncoC4 Agreement in its entirety for convenience with prior written notice to OncoC4.

I. Pfizer COVID-19 Vaccine Collaboration

On April 9, 2020, effective as of March 17, 2020, we entered into a Collaboration Agreement with Pfizer for the research and development of immunogenic compositions comprising RNA encoding a SARS-CoV-2 polypeptide or fragment thereof for prophylaxis against SARS-CoV-2 in humans, which we refer to as the Pfizer Corona Field. On January 29, 2021, effective as of March 17, 2020, we entered into an amended and restated Collaboration Agreement with Pfizer for the research, development and commercialization of immunogenic compositions comprising RNA in the Pfizer Corona Field, which we refer to as the Pfizer Agreement.

We and Pfizer agreed to collaborate on research, development and commercialization in the Pfizer Corona Field worldwide (excluding the Fosun Collaboration Territory), which we refer to as the Pfizer Collaboration Territory. The details of such activities are set forth in a research and development plan that is governed by a joint steering committee. Each party bears its own personnel and capital expenditures costs, but the parties will share the costs of all other agreed development activities (including the costs of manufacturing material for use in clinical trials) evenly. Each party will, in good faith, seek funding from government funds, non-governmental organizations and other third-party organizations to support their research and development activities. Under the Pfizer Agreement, Pfizer is leading clinical development of and is seeking regulatory approval for any candidates or products in the United States and we are leading clinical development of and are seeking regulatory approval for any candidates or products in the European Union, and we will agree on a strategy for all other countries in the Pfizer Collaboration Territory on an ongoing basis through the joint steering committees.

BioNTech can solely commercialize the vaccine in Germany and Türkiye (collectively referred to as the BioNTech Commercialization Territory, which is a subset of the Pfizer-Collaboration Territory). We have the option to opt-out of commercializing the vaccine in Germany and/or Türkiye, whereupon such countries will become part of the Pfizer Commercialization Territory of the Pfizer Collaboration Territory.

Pfizer has the right to commercialize any approved COVID-19 vaccine in the rest of the Pfizer Collaboration Territory. On a country-by-country basis in relation to the United Arab Emirates, Southeast Asia, and certain developing countries, if we obtain funding from a third-party organization that obligates us to commercialize an approved vaccine in such country, we are obligated to request from Pfizer in writing a decision as to whether Pfizer wishes to commercialize or distribute such vaccine in such country in accordance with the requirements agreed with the third-party funder. If Pfizer elects not to commercialize the vaccine in such country, then such country shall become a part of the BioNTech Commercialization Territory.

If our Collaboration Agreement with Fosun expires or is otherwise terminated for any reason, as between us and any international pharmaceutical group headquartered outside of China, we have granted Pfizer a right of first negotiation to expand the Pfizer Commercialization Territory to include the Fosun Territory. See “Fosun-COVID-19 Collaboration” below for more information on the Fosun Agreement.

We and Pfizer share responsibilities for manufacturing and supplying our approved COVID-19 vaccines. If there is insufficient supply to satisfy the entire demand for vaccines in the Pfizer Collaboration Territory, we and Pfizer have agreed to determine by mutual consent the allocation of supplies on a fair and equitable basis, subject also to any applicable law, export controls, and taking into account any government supply obligations, or supply obligations included in any agreement reached with a third-party funding organization.

Under the Pfizer Agreement, we have granted Pfizer an exclusive, sublicensable license in the Pfizer Collaboration Territory under certain of our intellectual property, including our patents and know-how, relating to uridine RNA, modified RNA and replicons in the Pfizer Corona Field as well as certain intellectual property in-licensed by us from third parties, to use, research, develop, manufacture, commercialize and otherwise exploit candidates and products selected under the Pfizer Agreement. We undertake to maintain in full effect all intellectual property licenses held by us at the time we entered into the Pfizer Agreement and not to modify or amend any such license in a manner that would adversely affect any of the rights granted to Pfizer under the Pfizer Agreement. We are obligated to notify Pfizer of any breach of our current licenses and may be obligated to take steps to maintain Pfizer’s access to any intellectual property licensed under such licenses. Under the Pfizer Agreement, we are obligated to indemnify Pfizer with respect to certain patent infringement claims that Pfizer elects to control.

During the term of the Pfizer Agreement and a certain period thereafter, we and Pfizer have committed not to research, develop, manufacture, commercialize or otherwise exploit immunogenic compositions comprising RNA in the Pfizer Corona Field, or exploit vaccine candidates or products developed under the agreement for any use, other than pursuant to the Pfizer Agreement, provided, however, that Pfizer shall have the right to work as a contract manufacturer for a third party and Pfizer shall not be precluded from acquiring a third party, or being acquired by a third party, that at the

time of acquisition is active in the development or commercialization of an immunogenic composition comprising mRNA in the Pfizer Corona Field.

On April 9, 2020, Pfizer also subscribed for \$113 million of our ordinary shares under a separate investment agreement. In addition, under the Pfizer Agreement, Pfizer made an upfront payment of \$72 million and agreed to make potential payments of up to \$563 million upon the achievement of specified regulatory and commercial milestones. We and Pfizer agreed to share development costs equally. We and Pfizer will share the gross profits from commercializing a vaccine evenly, as well as the costs for shipping. The Pfizer Agreement continues for so long as either at least a vaccine is being developed for use in the Pfizer Collaboration Territory or a vaccine is being commercialized anywhere in the Pfizer Collaboration Territory. In addition to termination rights granted to each party in the case of the other party's uncured material breach, Pfizer may terminate the agreement (i) upon our insolvency or (ii) on a country-by-country basis or in its entirety for convenience upon one (1) year's prior written notice provided that any such termination shall not become effective less than two (2) years from the first commercial sale of an approved vaccine.

J. Pfizer-Influenza Collaboration

On July 20, 2018, we and BioNTech RNA entered into a Research Collaboration and License Agreement with Pfizer, or the Pfizer Influenza Agreement, for the research, development and Pfizer's commercialization of immunogenic compositions comprising modified RNA and/or replicon technology for prophylaxis against influenza in humans, which we refer to as the Pfizer Influenza Agreement Field.

We and Pfizer agreed to collaborate on the research in the Pfizer Influenza Agreement Field for an initial period of three years, ending in August 2021. The details of such research were set forth in a research plan that is governed by a Joint Steering Committee, with Pfizer holding the final decision-making right. Each party will bear its own costs under the research plan. The research term will be extended automatically by a reasonable amount of time if the activities or deliverables under the research plan are delayed due to our material breach of our research obligations under the research plan. In addition, Pfizer may unilaterally extend the research term by up to a year by making an additional payment to us.

After the research term expires, Pfizer has the sole responsibility, authority and control of the development, manufacturing and commercialization of all candidates and products. Pfizer undertakes to use commercially reasonable efforts to seek regulatory approval for one product in the United States and in two countries out of France, Germany, Italy, Spain, the United Kingdom and Japan, and to commercialize such product in such countries where such product has received regulatory approval.

Under the Pfizer Influenza Agreement, we grant to Pfizer an exclusive, worldwide, sublicensable license under certain of our intellectual property, including our patents and know-how, relating to replicons and modified RNA in the Pfizer Influenza Agreement Field as well as certain intellectual property in-licensed by us from third parties, to use, research, develop, manufacture, commercialize and otherwise exploit candidates and products selected under the Pfizer Influenza Agreement. We also grant to Pfizer a non-exclusive, royalty-free, sublicensable license under all intellectual property controlled by us or our affiliates to use, develop, manufacture, commercialize and otherwise exploit candidates and products selected under the Pfizer Influenza Agreement in the Pfizer Influenza Agreement Field. We undertake to maintain in full effect all intellectual property licenses held by us at the time we entered into the agreement and to not modify or amend any such license in a manner that would adversely affect any of the rights granted to Pfizer under the Pfizer Influenza Agreement. We are obligated to notify Pfizer of any breach of our current licenses and may be obligated to take steps to maintain Pfizer's access to any intellectual property licensed under such licenses.

We also granted Pfizer a right of first negotiation to acquire an exclusive worldwide license under certain intellectual property controlled by us for Pfizer to develop, manufacture and commercialize immunogenic products comprising RNA for prophylaxis against respiratory syncytial virus or human cytomegalovirus. The right of first negotiation may be exercised until the end of the research term.

In consideration of the rights granted to Pfizer under the agreement, Pfizer subscribed to shares in BioNTech AG under a separate investment agreement. In addition, under the Pfizer Influenza Agreement, Pfizer made an upfront payment of \$50 million and agreed to potential payments of up to \$325 million upon the achievement of specified development, regulatory and commercial milestones. Pfizer further agreed to a mid-single digit to very low double-digit tiered royalty on net sales if a product is commercialized. Royalties are subject to stacking provisions. The obligation of Pfizer to pay royalties ends, on a country-by-country and a product-by-product, basis upon the later of (i) the expiration of the last valid licensed patent right covering such product category in such country, (ii) 10 years after the first commercial sale of a product of such product category in such country and (iii) the lapse of regulatory data exclusivity for the first product in

such product category in such country. There are only two product categories: one for modified RNA and a second for replicon products.

During the term of the Pfizer Influenza Agreement, we have committed not to research, develop, manufacture, commercialize or otherwise exploit immunogenic compositions comprising RNA in the Pfizer Influenza Agreement Field other than pursuant to the Pfizer Influenza Agreement.

The Pfizer Influenza Agreement ends on a country-by-country basis upon expiration of the last royalty term for any product in that country. Thereafter, the licenses granted to Pfizer with respect to such product in such country will convert into a perpetual, exclusive, fully paid-up and royalty-free license. In addition to termination rights granted to each party in the case of the other party's uncured material breach, Pfizer may terminate the agreement, in whole or in part, for convenience and with or without reason at any time upon 60 days' prior written notice. In addition, Pfizer is entitled to terminate the agreement and initiate a technology transfer of certain intellectual property if one of its key competitors acquires control over us.

X. Government Regulation

Government authorities in the United States at the federal, state and local levels, and in the European Union and other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, record-keeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting and import and export of pharmaceutical products, including biological products. In addition, some jurisdictions regulate the pricing of pharmaceutical products. The processes for obtaining marketing approvals in the United States and in other jurisdictions, along with subsequent compliance with applicable statutes and regulations and other requirements of regulatory authorities, require the expenditure of substantial time and financial resources.

A. Regulation and Procedures Governing Approval of Drug and Biological Products in the United States

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations and biologics under the FDCA, the Public Health Service Act, or the PHSA, and their implementing regulations. Both drugs and biologics are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject a sponsor or marketing authorization (BLA/NDA) holder to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, clinical hold, untitled or warning letters, voluntary or mandatory product recalls, market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

A sponsor seeking approval to market and distribute a new drug or biological product in the United States generally must satisfactorily complete each of the following steps:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with applicable regulations, including the FDA's good laboratory practices, or GLP, regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by the IRB representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance applicable regulations, including GCP;
- preparation and submission to the FDA of a NDA for a drug product, or a BLA for a biological product requesting marketing approval for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development, evidence of safety, purity and potency from preclinical testing and clinical trials, and proposed labeling;
- review of the product by an FDA advisory committee, if applicable;

- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with current GMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the clinical study sites to assure compliance with applicable regulations and GCP, and the integrity of clinical data in support of the NDA or BLA;
- payment of user fees and securing FDA approval of the NDA or BLA; and
- compliance with applicable regulations post approval, including any post-approval requirements, such as the potential requirement to implement a REMS and to conduct any post-approval studies required by the FDA.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates and any future product candidates will be granted on a timely basis, or at all.

Preclinical Studies and Investigational New Drug Application

Before testing any drug or biological product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as animal studies to evaluate the potential for activity and toxicity. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, are submitted to the FDA as part of an IND application. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that patients will be exposed to unreasonable health risks, and places the trial on a clinical hold. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trial can begin.

As a result, submission of the IND may result in the FDA not allowing the trial to commence or not be conducted on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND process, it may choose to impose a partial or complete clinical hold. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. A clinical hold issued by the FDA may therefore delay either a proposed clinical study or cause suspension of an ongoing study, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigation may proceed. This could cause significant difficulties in completing planned clinical trials in a timely manner.

The FDA may impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance.

Human Clinical Trials in Support of an NDA or a BLA

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of qualified principal investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all patients provide their informed consent for their participation. Clinical trials are conducted under study protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety, dosing procedures and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of the NDA or BLA so long as the clinical trial is well-designed and well-conducted in accordance with GCP, including review and approval by an independent ethics committee, and the FDA is able to validate the study data through an onsite inspection, if necessary.

Further, each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors and the safety of patients. An IRB must operate in compliance with FDA regulations. The FDA, IRB, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or that the

patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and receive periodic reports regarding the investigation from the investigators. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee, or DSMB. This group may recommend continuation of the study as planned, changes in study conduct, or cessation of the study at designated check points based on access to certain data from the study.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- Phase 1 clinical trials (or Phase 1) are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics in healthy humans or, on occasion, in patients, such as in the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers.
- Phase 2 clinical trials (or Phase 2) are generally conducted in a limited patient population to identify possible adverse effects and safety risks, preliminarily evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger Phase 3 clinical trials. When a drug is intended to treat life-threatening or severely debilitating illnesses, and particularly for rare diseases, the FDA may accept well-controlled Phase 2 clinical trials as adequate to provide sufficient data on the drug's safety and effectiveness to support a decision on its approvability for marketing, in which case Phase 3 clinical trials would not be required.
- Phase 3 clinical trials (or Phase 3) proceed if the Phase 2 clinical trials demonstrate that a certain dose or dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population, often at geographically dispersed clinical trial sites, to gather additional information about safety and effectiveness necessary to evaluate the overall benefit-risk relationship of the product and to provide the basis for product labeling.

In some cases, the FDA may approve an NDA or a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and/or effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials (or Phase 4). These studies may be used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement or to request a change in the product labeling. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials or to comply with post approval commitments could result in withdrawal of approval for products.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other trials, tests in laboratory animals or *in vitro* testing that suggest a significant risk for patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. The FDA or the sponsor or its DSMB may suspend a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the new drug candidate or biological product candidate has been associated with unexpected serious harm to patients.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then

made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

Compliance with GMP Requirements

Before approving an NDA or a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in full compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. Among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final drug or biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug or biological product does not undergo unacceptable deterioration over its shelf life. In particular, the PHSA emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined.

Manufacturers and others involved in the manufacture and distribution of drugs and biological products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process.

The manufacturing facilities may be subject to periodic announced and unannounced inspections by government authorities to ensure compliance with GMPs and other laws. Manufacturers may have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

Review and Approval of an NDA or a BLA

The results of product candidate development, preclinical testing and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of an NDA or a BLA requesting a license to market the product. These applications must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling. The FDA adjusts the Prescription Drug User Fee Act, or PDUFA, user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether the NDA or BLA is sufficient to accept for filing based on the agency's threshold determination that it is substantially complete so as to permit substantive review. Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to complete its initial review of a standard application and respond to the sponsor within ten months of the 60-day filing date, and for a priority review application within six months. The FDA does not always meet its PDUFA goal dates for standard and priority NDA or BLA applications, and its review goals are subject to change from time to time. The review process may often be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may also be extended by three months if the FDA requests or if the sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

The FDA reviews NDA and BLA applications to determine, among other things, whether the proposed product is safe and potent, and/or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with GMP requirements to assure and preserve the product's identity, safety, strength, quality, potency and purity. On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of clinical trial sites to assure compliance with GCPs, the FDA may issue an approval letter, denial letter or complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. Under the FDCA, the FDA may approve an NDA if it determines that the product is safe and effective for its intended use, the benefits of the drug outweigh any risks, and the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality and purity. Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure and potent. If the application is not approved, the FDA may

issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the application, and when possible will outline recommended actions the sponsor might take to obtain approval of the application. If a complete response letter is issued, the sponsor may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

Sponsors that receive a complete response letter who elect to address the deficiencies may submit to the FDA information that represents a complete response to the issues identified by the FDA in the response letter. Such resubmissions are classified under PDUFA as either Class 1 or Class 2, based on the information submitted by a sponsor in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to review and act on a Class 1 resubmission with two months of receipt and, with respect to a Class 2 resubmission, within six months of receipt. The FDA will not approve an application until issues identified in the complete response letter have been addressed.

The FDA may also refer the application to an Advisory Committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. In particular, the FDA may refer applications for novel drug or biological products or drug or biological products that present difficult questions of safety or efficacy to an advisory committee. Typically, an Advisory Committee is a panel of independent experts, including clinicians and other scientific experts. The FDA is not bound by the recommendations of an Advisory Committee, but it considers such recommendations carefully when making decisions.

If the FDA approves a new product, it may limit the approved indications for use of the product, or limit the approval to specific dosages. It may also require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including risk evaluation and mitigation strategies, or REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without a REMS, if required. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA may designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation.

The FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request that the FDA designate the drug or biologic as a fast track product at any time during the clinical development of the product. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. Fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or the FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect

to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to facilitate the design of clinical trials in an efficient manner.

The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application to six months (compared to 10 months under standard review).

Fast track designation, priority review and breakthrough therapy designation may expedite the development or approval process, but do not change the standards for approval.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has stated that although it has limited experience with accelerated approvals based on intermediate clinical endpoints, such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, may lead the FDA to withdraw the product from the market. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Accelerated approval pathways are available for regenerative medicine therapies that meet certain conditions. Regenerative medicine therapies include cell therapies (both allogeneic and autologous), therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except those regulated under section 361 of the PHSA. Human gene therapies, including genetically modified cells, that lead to a sustained effect on cells or tissues, may also meet the definition of a regenerative medicine therapy, as may xenogeneic cell products.

Regenerative medicine therapies designed to treat, modify, reverse or cure serious conditions are eligible for FDA's expedited programs, including fast track designation, breakthrough therapy designation, priority review and accelerated approval, if they meet the criteria for such programs. They may also be eligible for Regenerative Medicine Advanced Therapy Designation, or RMAT designation.

An investigational drug is eligible for RMAT designation if it meets the definition of regenerative medicine therapy, it is intended to treat, modify, reverse or cure a serious condition, and preliminary clinical evidence indicates that the regenerative medicine therapy has the potential to address unmet medical needs for such condition. An unmet medical need is a condition whose treatment or diagnosis is not addressed adequately by available therapy.

RMAT designation confers all the benefits of the fast track and breakthrough therapy designation programs, including early interactions with the FDA. The FDA reviews each application on a case-by-case basis to determine whether the clinical evidence is sufficient to support RMAT designation, considering factors such as the rigor of data collection, the consistency and persuasiveness of the outcomes, the number of patients, and the severity, rarity or prevalence of the condition, among other factors. The FDA may decline to grant RMAT designation if it finds the clinical evidence insufficient.

RMAT designation may expedite the development or approval process, but it does not change the standards for approval.

Emergency Use Authorizations

The Secretary of Health and Human Services has the authority to authorize unapproved medical products, including vaccines, to be marketed in the context of an actual or potential emergency that has been designated by government officials. The COVID-19 pandemic has been designated such a national emergency. After an emergency has been announced, the Secretary of Health and Human Services may authorize the issuance of, and the FDA Commissioner may issue, Emergency Use Authorizations, or EUAs, for the use of specific products based on criteria established by statute, including that the product at issue may be effective in diagnosing, treating, or preventing serious or life-threatening diseases when there are no adequate, approved, and available alternatives. An EUA is subject to additional conditions and restrictions and is product-specific. An EUA terminates when the emergency determination underlying the EUA terminates or full approval is obtained. An EUA is not a long-term alternative to obtaining FDA approval, licensure, or clearance for a product. FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, so it is not possible to predict how long an EUA may remain in place.

Post-Approval Regulation

If regulatory approval for marketing of a product or for a new indication for an existing product is obtained, the sponsor will be required to comply with rigorous and extensive post-approval regulatory requirements as well as any post-approval requirements that the FDA has imposed on the particular product as part of the approval process. The sponsor will be required, among other things, to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including GMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the BLA holder and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with GMP regulations and other regulatory requirements. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market study requirements or clinical trial requirements to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;

- fines, untitled letters or warning letters or holds on post-approval clinical trials;
- adverse publicity;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions, fines, debarment, disgorgement of profits or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Orphan Drug Designation

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a disease or condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making available the product for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for certain financial incentives, including tax advantages and, if the product receives the first FDA approval for the indication for which it has orphan designation, market exclusivity for seven years following the date of the product's marketing approval. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Once a product receives orphan drug designation from the Office of Orphan Products Development at the FDA, the product must then go through the review and approval process like any other product.

In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first product. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor, the manufacturer makes a showing of clinical superiority over the product with orphan exclusivity, or the sponsor is unable to provide sufficient quantities.

Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors who are planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must also submit pediatric study plans prior to the assessment data, and no later than 60 calendar days following an end-of-Phase 2 meeting with the FDA or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. Pediatric study plans must contain an outline of the proposed pediatric study or studies the sponsor plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The sponsor, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the sponsor may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA or a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation and impact of the BPCIA is subject to significant uncertainty.

B. Regulation and Procedures Governing Approval of Medicinal Products in the European Union

The process governing approval of medicinal products, including biological medicinal products and advanced therapy medicinal products, or ATMPs, which comprise gene therapy products, somatic cell therapy products and tissue-engineered products, in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical and clinical studies to establish the safety and efficacy of the medicinal product for each proposed indication. Moreover, an applicant must also demonstrate the ability to manufacture the product to a suitable quality.

Clinical Trial Approval

Until recently, pursuant to the Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, a sponsor must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the sponsor may only start a clinical trial at a specific study site after the independent ethics committee has issued a favorable opinion.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which took effect on January 31, 2022 and replaced the Clinical Trials Directive 2001/20/EC. Commission Implementing Regulation (EU) 2017/556 replaced the GCP Directive 2005/28/EC. The Regulation has overhauled the former system of approvals for clinical trials in the European Union. Specifically, the Regulation, which is directly applicable in all member states, aims to simplify and streamline the approval of clinical trials in the European Union. For instance, Regulation (EU) No 536/2014 enables sponsors to submit one online application via a single online platform known as the Clinical Trials Information System (CTIS) for approval to run a clinical trial in several European countries, making it more efficient to carry out such multinational trials. It provides for strictly defined deadlines for the assessment of clinical trial applications. This means that one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement, although the clinical trial approval is still granted by each national competent authority. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees.

Pursuant to transitional provisions under Regulation (EU) No 536/2014, trials for which a request for approval was submitted prior to January 31, 2022 may continue under the national implementations of the Directives until January 31, 2025. In addition, until January 30, 2023, clinical trial sponsors could use CTIS to apply to run a clinical trial under the Regulation or could choose to apply to run a trial under the Clinical Trials Directive. However, since January 31, 2023, clinical trial sponsors have needed to use CTIS to apply to start a new clinical trial in the EU/EEA and such trials must be run under the Regulation. By January 31, 2025, any ongoing trials approved under the Clinical Trial Directive will fall under the Regulation and information about them must be transferred to CTIS.

Under either regime, clinical trials must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization, or ICH, guidelines on GCP. Additional GCP guidelines from the European Commission, with a focus on traceability, apply to clinical trials of ATMPs. If the sponsor of the clinical trial is not established within the European Union, it must appoint an entity within the European Union to act as its legal representative.

The clinical trial application must be accompanied by a copy of the trial protocol and an investigational medicinal product dossier with supporting information prescribed by applicable legislation as further detailed in applicable guidance documents. Moreover, the sponsor must take out a clinical trial insurance policy, and in most European Union countries the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

The sponsor of a clinical trial must register the clinical trial in advance, and information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial will be made public as part of the registration. The results of the clinical trial must be submitted to the competent authorities and, with the exception of non-pediatric Phase 1 trials, will be made public at the latest within 12 months after the end of the trial.

During the development of a medicinal product, the European Medicines Agency, or EMA, and national medicines regulators within the European Union provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use, or CHMP. A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future marketing authorization application of the product concerned.

Marketing Authorization

To obtain a marketing authorization for a product under the European Union regulatory system, a sponsor must submit a marketing authorization application, or MAA, either under the centralized procedure administered by the EMA or

one of the procedures administered by competent authorities in European Union member states (decentralized procedure, mutual recognition procedure, or if the product is to be approved in only one member state, the national procedure).

All application procedures require an application in the common technical document, or CTD, format, which includes the submission of detailed information about the manufacturing and quality of the product, and nonclinical and clinical trial information. There is an increasing trend in the European Union toward greater transparency and, while certain of the manufacturing or quality information is currently generally protected as commercially confidential information, the EMA and national regulatory authorities are now liable to disclose much of the nonclinical and clinical information in marketing authorization dossiers, including the full clinical study reports, in response to freedom of information requests after the marketing authorization has been granted. In October 2014, the EMA adopted a policy under which clinical study reports would be posted on the agency's website following the grant, denial or withdrawal of a MAA, subject to procedures for limited redactions and protection against unfair commercial use. The operation of this policy has been suspended in recent years due to priorities. However, it continues to apply the policy to COVID-19 vaccines and therapeutics. A similar transparency requirement is contained in the Clinical Trials Regulation (EU) No 536/2014.

A marketing authorization may be granted only to a sponsor established in the European Union. Regulation (EC) No. 1901/2006 on medicinal products for pediatric use provides that prior to obtaining a marketing authorization in the European Union in the centralized procedure, a sponsor must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver or deferral for one or more of the measures included in the Pediatric Investigation Plan.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union and European Economic Area member states. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines (including vaccines) produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure is optional.

Under the centralized procedure, the CHMP established at the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions from the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health determined by three cumulative criteria: (i) the seriousness of the disease (e.g., heavy disabling or life-threatening diseases) to be treated, (ii) the absence or insufficiency of an appropriate alternative therapeutic approach, and (iii) anticipation of high therapeutic benefit.

If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment. The Committee for Advanced Therapies, or CAT, is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CAT is primarily responsible for the scientific evaluation of ATMPs and prepares a draft opinion on the quality, safety and efficacy of each ATMP for which a MAA is submitted. The CAT's opinion is then taken into account by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits and risks identified. Although the CAT's draft opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion if it provides detailed scientific justification. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines, which are not legally binding, provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, inter alia, the preclinical studies required to characterize ATMPs, the manufacturing and control information that should be submitted in a MAA; and post-approval measures required to monitor patients and evaluate the long term efficacy and potential adverse reactions of ATMPs.

The European Commission may grant a so-called "marketing authorization under exceptional circumstances." Such authorization is intended for products for which the applicant can demonstrate that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or in the present state of scientific knowledge, comprehensive information cannot be provided, or it would be contrary to

generally accepted principles of medical ethics to collect such information. Consequently, marketing authorization under exceptional circumstances may be granted subject to certain specific obligations, which may include the following:

- the applicant must complete an identified program of studies within a time period specified by the competent authority, the results of which form the basis of a reassessment of the benefit/risk profile;
- the medicinal product in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, possibly in a hospital, and in the case of a radio-pharmaceutical, by an authorized person; and
- the package leaflet and any medical information must draw the attention of the medical practitioner to the fact that the particulars available concerning the medicinal product in question are as yet inadequate in certain specified respects.

A marketing authorization under exceptional circumstances is subject to annual review to reassess the risk-benefit balance in an annual re-assessment procedure. Continuation of the authorization is linked to the annual reassessment and a negative assessment could potentially result in the marketing authorization being suspended or revoked. The renewal of the marketing authorization of a medicinal product under exceptional circumstances follows the same rules as a “normal” marketing authorization. After five years, the marketing authorization will then be renewed under exceptional circumstances for an unlimited period, unless the EMA decides, on justified grounds, to proceed with one additional five-year renewal.

The European Commission may also grant a so-called “conditional marketing authorization” prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional marketing authorizations may be granted for product candidates (including medicines designated as orphan medicinal products and vaccines) if the CHMP finds that all the following requirements are met:

- the benefit-risk balance of the product is positive;
- it is likely that the applicant will be able to provide comprehensive data;
- unmet medical needs will be fulfilled; and
- the benefit to public health of the medicinal product’s immediate availability on the market outweighs the risks due to need for further data.

A conditional marketing authorization will contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, manufacturing information and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization. Once comprehensive data on the medicinal product have been obtained, the marketing authorization may be converted into a standard marketing authorization which is no longer subject to specific obligations. Initially, this is valid for five years, but can be renewed for unlimited validity.

For COVID-19 vaccines to date, the EMA has followed a so-called ‘rolling review’ process, an *ad hoc* procedure by which data is assessed as it becomes available with the aim of granting a conditional marketing authorization.

The European Union medicines rules expressly permit the member states to adopt national legislation prohibiting or restricting the sale, supply or use of any medicinal products containing, consisting of or derived from a specific type of human or animal cell, such as embryonic stem cells.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing member states. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the product on the European Union market (in the case of the centralized

procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (referred to as the “sunset” clause).

Emergency Use Authorizations

The European Union medicines rules, as implemented into the national laws of the EU member states, permit national authorities to authorize temporarily the distribution of an unapproved medicinal product in certain emergency situations, including suspected or confirmed spread of pathogenic agents. Such an Emergency Use Authorization (EUA) (sometimes referred to as a “temporary exemption,” i.e., a temporary exemption from the requirement to obtain a marketing authorization) would apply for the duration of the emergency only and would be limited to the member state in which it has been issued. When considering whether to grant an EUA, the relevant member state decides, which data it requires for the grant of the EUA. For COVID-19 vaccines to date, the EU member states have not relied on EUAs. Rather products have followed the centralized procedure combined with a rolling review of data with a view to granting conditional marketing authorizations. Member states have relied on EUAs to permit the distribution and use of certain unapproved medicines in unapproved indications to assist in the treatment of COVID-19 patients.

Regulatory Requirements after Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the European Union’s stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs. All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety or efficacy studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.

In addition, the manufacturing of authorized products, for which a separate manufacturer’s license is mandatory, must also be conducted in strict compliance with the EMA’s GMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in the manufacturing, processing and packing of products to assure their safety and identity. Specifically, medicinal products may only be manufactured in the European Union, or imported into the European Union from another country, by the holder of a manufacturing/import authorization from the competent national authority. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with European Union standards of good manufacturing practice, or GMP, before releasing the product for commercial distribution in the European Union or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of products and/or the general public, are strictly regulated in the European Union. In principle, all advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines (including vaccines) is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under Directive 2001/83/EC, as amended, the details and the enforcement of these rules are governed by regulations in each member state and can differ from one country to another.

The enforcement actions and consequences for non-compliance with the EU legislation are similar to those listed above for the United States. For centrally approved products in the EU, there is the possibility of fines for regulatory non-compliance with certain of the legal requirements, including in relation to obligations regarding placing the product on the market, safety monitoring and pediatric compliance.

Human Cells and Tissues

Human cells and tissues that are intended for human applications but that do not fall within the scope of rules governing medicinal products or medical devices are not subject to premarket review and approval, nor do they require extensive preclinical and clinical testing. However, there are European Union rules governing the donation, procurement, testing and storage of human cells and tissues intended for human application, whether or not they are ATMPs. These rules also cover the processing, preservation and distribution of human cell and tissues that are not ATMPs. Establishments that conduct such activities must be licensed and are subject to inspection by regulatory authorities. Such establishments must implement appropriate quality systems and maintain appropriate records to ensure that cells and tissues can be traced from the donor to the recipient and vice versa. There are also requirements to report serious adverse events and reactions linked to the quality and safety of cells and tissues. More detailed rules may exist at the national level.

Named Patient Supplies and Compassionate Use Programs

The European Union medicines rules allow individual member states to permit the supply of a medicinal product without a marketing authorization to fulfill special needs, where the product is supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of a healthcare professional and for use by an individual patient under his direct personal responsibility. This may in certain countries also apply to products manufactured in a country outside the European Union and imported to treat specific patients or small groups of patients.

Some member state laws also provide for compassionate use on a “cohort” basis, subject to review and approval of the cohort program based on the local laws in the member state.

Orphan Drug Designation and Exclusivity

Regulation (EC) No. 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (i) a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union when the application is made, or (ii) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the product in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the sponsor must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the product has to be of significant benefit compared to products available for the condition.

An orphan drug designation provides a number of benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized European Union marketing authorization. Marketing authorization for an orphan drug leads to a 10-year period of orphan market exclusivity. During this orphan market exclusivity period, neither the EMA nor the European Commission or the member states can accept an application or grant a marketing authorization for a “similar medicinal product.” A “similar medicinal product” is defined as a medicinal product containing a similar active substance or substances as contained in a currently authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation.

European Data Collection and Data Protection Laws

We are required to comply with strict data protection and privacy legislation in the jurisdictions in which we operate, including the General Data Protection Regulation (EU) 2016/679, or GDPR. The GDPR governs our collection and use of personal data in the European Union relating to individuals (e.g., patients). The GDPR imposes several requirements on organizations that process such data, including: to observe core data processing principles; to comply with various accountability measures; to provide more detailed information to individuals about data processing activities; to establish a legal basis to process personal data (including enhanced consent requirements); to maintain the integrity, security and confidentiality of personal data; and to report personal data breaches. The GDPR also restricts the transfer of personal data outside of the European Economic Area (e.g., to the United States and other countries that are not deemed to provide adequate protection under their domestic laws). The GDPR may impose additional responsibility and liability in relation to personal data that we process, and require us to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. Failure to comply with the requirements of the GDPR and related national data protection laws of European

Union member states may result in a variety of enforcement measures, including significant fines and other administrative measures. The GDPR has introduced substantial fines for breaches of the data protection rules, increased powers for regulators, enhanced rights for individuals, and new rules on judicial remedies and collective redress. We may be subject to claims by third parties, such as patients or regulatory bodies, that we or our employees or independent contractors inadvertently or otherwise breached GDPR and related data protection rules. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we do not prevail, we could be required to pay substantial fines and/or damages and could suffer significant reputational harm. Even if we are successful, litigation could result in substantial cost and be a distraction to management and other employees.

C. Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. Even if our product candidates are approved for marketing, sales of such product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the United States (such as Medicare and Medicaid), commercial health insurers and managed care organizations, provide coverage and establish adequate reimbursement levels for such product candidates. In the United States, the member states of the European Union and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Reimbursement rules and levels are not harmonized in the European Union and therefore differ from member state to member state. Patients are unlikely to use any product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services and imposing controls to manage costs.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, and the cost of these studies would be in addition to the costs required to obtain FDA or other comparable marketing approvals. Even after pharmacoeconomic studies are conducted, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. For example, the payor may require co-payments that patients find unacceptably high. Further, one payor's determination to provide coverage for a product does not assure that such coverage will continue or that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party reimbursement and coverage may not be adequate to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. The insurance coverage and reimbursement status of newly approved products for orphan diseases is particularly uncertain, and failure to obtain or maintain adequate coverage and reimbursement for any such product candidates could limit a company's ability to generate revenue.

The containment of healthcare costs also has become a priority of U.S. federal and state and other non-U.S. governments as well as other third-party payors such as statutory health insurance funds, and the prices of pharmaceuticals have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented or coverage may be ended in the future.

Outside the United States, we will face challenges in ensuring and obtaining adequate coverage and payment for any product candidates we may develop. Pricing of prescription pharmaceuticals is subject to governmental control in many countries, including in particular the member states of the European Union. Pricing negotiations with governmental authorities or other third-party payors such as statutory health insurance funds can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial or non-interventional study that

compares the cost effectiveness of any product candidates we may develop to other available therapies. The conduct of such a clinical trial or study could be expensive and result in delays in our commercialization efforts.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. The European Union recently adopted Regulation (EU) 2021/2282 on health technology assessment, which provides a framework for member states to cooperate on health technology assessments at the EU level. The Regulation is directly applicable in all EU member states and will apply from January 12, 2025, although pricing will still be determined nationally. Moreover, at the national level, European Union member states may restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Member states may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products in the marketplace. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel trade (arbitrage between low-priced and high-priced member states) can further reduce prices. Special pricing and reimbursement rules may apply to orphan drugs. Inclusion of orphan drugs in reimbursement systems tend to focus on the medical usefulness, need, quality and economic benefits to patients and the healthcare system as for any product. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results-based rules of reimbursement may apply. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries.

For COVID-19 vaccine candidates in the European Union, no pricing and reimbursement or health technology assessments discussions have taken place with the respective health insurances and competent bodies at a national member state level. Currently, COVID-19 vaccine candidates are supplied in the European Union based on vaccine supply agreements with the European Commission that is acting on behalf and in the name of the member states of the European Union.

D. United Kingdom

On June 23, 2016, in a national referendum, a majority of the electorate voted in favor of the United Kingdom leaving the European Union (commonly referred to as “Brexit”). On March 29, 2017, the United Kingdom Government formally notified the European Union of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on the European Union. The United Kingdom formally left the European Union on January 31, 2020. Pursuant to the terms of the Withdrawal Agreement between the European Union and the United Kingdom, a transitional period ran between February 1, 2020 and December 31, 2020, during which all applicable EU law, including the regulation of medicinal products, applied to and in the United Kingdom. This transitional period has now expired. On December 24, 2020, the United Kingdom and the European Union announced that they have reached agreement on the terms of their future relationship as set out in the Trade and Cooperation Agreement (“TCA”). The European Union and the United Kingdom had agreed to provisionally apply the terms of the TCA, while the formal execution was still ongoing. The TCA formally entered into force on May 1, 2021. While the TCA governs tariff and quota free trade between the United Kingdom and the European Union markets, it does not provide for regulatory alignment. The regulatory framework for medicinal products in the United Kingdom is predominantly derived from European Union law. The UK currently offers different routes to obtain a marketing authorisation: (a) a national application route with a 150-day assessment timeline, excluding clock stops or (b) a reliance route by which a company relies on a positive CHMP opinion with a 67-day assessment timeline. The original reliance route was available to companies until December 31, 2023, and has been replaced by the International Recognition Procedure since January 1, 2024.

Domestic United Kingdom law provided that all existing European Union law in force on December 31, 2020 was retained in UK national law, subject to certain revisions that became necessary as a result of Brexit.

However, the Retained EU Law (Revocation and Reform) Act 2023 came into force on January 1, 2024. This revoked some retained EU laws (although not any relating to medicines regulation). All other retained EU laws have been renamed as “assimilated laws” and are no longer subject to the EU principles of interpretation. Thus, while at least initially the United Kingdom and the European Union laws relating to medicines are largely aligned, there is the potential for further divergence in the future.

Under the terms of the Northern Ireland Protocol to the Withdrawal Agreement, European Union law continues to apply to and in Northern Ireland. The terms of the Protocol are subject to renegotiation between the United Kingdom and the European Union. In March 2023, the Northern Ireland Protocol was adjusted by the Windsor Framework, which is another post-Brexit agreement between the EU and the UK. The Windsor Framework will be implemented gradually through into 2025 and aims to make it easier to move certain goods, including medicines, from Great Britain to Northern Ireland.

E. Greater China

Mainland China

Similar to the United States and the European Union, Mainland China has rules governing the approval for development and commercialization of drugs, including specialized rules for vaccines. China’s drug law and regulations require that the National Medical Products Administration’s, or NMPA’s, Center for Drug Evaluation, or CDE, approve a clinical trial application prior to initiating a study to support the safety and effectiveness of a drug, including a therapeutic or preventive biologic (i.e., a vaccine). This clinical trial application and the testing procedure that may precede it can be expedited if there is a pressing declared health emergency, as was the case with COVID-19.

Once approved, vaccine clinical trials must be conducted at sites that are qualified disease prevention and control, or CDC, institutions and grade III hospitals, and the implementation of the trial must be in accordance with China’s general drug and specialized vaccine good clinical practice regulations and related guidelines. Other drug trials must be conducted at designated hospital sites in accordance with China’s general drug good clinical practice rules. Furthermore, prior to the commencement of the clinical trial in China each site’s ethics committee must approve the trial, and the Ministry of Science and Technology must approve the use of human samples containing genetic material and related genetic data. The human genetic resources, or HGR, approval requires a joint approval or record-filing application by the Chinese and foreign parties, setting forth the parties that will handle data and samples, the type and amount of samples that will be utilized during the study, the tests/analysis run, and the plans for storage or destruction, and the intellectual property sharing arrangement among the parties, among other items. If the research is exploratory (i.e., not tied to a program designed to obtain registration in China), patentable IP arising from the use of the HGR samples and data must be jointly owned by the Chinese and foreign parties. Once approved, the HGR approval/filing may require updates and amendments and additional procedures to transfer data to foreign parties that are not on the approval. A final report is due at the end of the study.

Once a clinical trial in China is complete and/or foreign data is assembled, a company may submit an application for a marketing authorization, or MA, of the drug. This procedure will include submission of clinical data, manufacturing information and test results, among other items, and may include an onsite pre-market verification by the NMPA. This application may be considered more quickly if the applicant qualifies for admission to various expedited programs, including breakthrough designation for drugs that are new to the world in some respect, treat life threatening or quality of life altering diseases and either have no comparator on the market or represent a significant clinical advantage over existing approved therapies. Conditional approval procedures permit approval of a drug based on earlier stage data, but subject continued marketing to the fulfillment of post-market conditions with a designation period of time, such as the completion of additional studies. Therapeutic biologics and small molecule drugs follow similar steps to approval for development and marketing. These steps are similar for drugs that are imported and those that are produced domestically in China. However, domestically produced drugs must be produced at a facility that also obtains a drug manufacturing license based, in part, on a pre-marketing good manufacturing practice inspection.

At both the clinical trial and MA stages, applicants for imported drugs must list a regulatory agent on the application. The agent must be an entity in China, and it assists the sponsor and marketing authorization holder, or MAH, with fulfilling its drug regulatory obligations in China. The agent of the MAH is jointly liable with the MAH for these drug regulatory obligations.

Once approved, vaccines may be procured by the CDC through platforms organized by the provincial governments. Vaccines in China must be sold and directly distributed by domestic manufacturers or general distributors appointed to represent overseas makers to municipal level CDCs, which handle allocation and distribution to points of vaccination in China. Distribution of other drugs occurs through procurement processes for sales at public hospitals and sales to private

hospitals or pharmacies. Distributors of all drugs must possess a MA for the drug they are distributing or a drug distribution license.

As is the case with all drugs, once on the market, MAHs will also have post-market obligations, including fulfillment of post-marketing commitments. In the case of vaccines, MAHs must pay compensation for injuries caused adverse events following inoculation, or AEFIs, if the vaccine is not one required as part of the National Inoculation Program. The government bears the cost of NIP vaccines and related AEFIs. All drug MAHs are subject to other post-market obligations for drug marketing authorization holders, including recalls, annual reporting, and inspections. Drug MAs must be renewed every five years, and supplemental applications, notifications, or reports may need to be submitted for major, moderate and minor changes, respectively, to the original registration (e.g., significant manufacturing changes).

Advertisements of prescription drugs, including vaccines, must be pre-approved and may only be placed in approved medical journals. Other forms of “academic promotion” may be performed by medical representatives who are authorized in writing by MAHs (or their agents) and their information filed on government designated websites. Medical representatives are permitted to provide information about the drug to health care professionals (in accordance with certain procedural rules) and collect feedback as to drug safety.

Hong Kong and Macao

Mainland China’s drug regulatory system does not apply in Hong Kong or Macao. These administrative regions are governed by separate laws on the development, approval, manufacturing, distribution and advertising and promotion of drugs, including vaccines. Similar rules restricting advertising and promotional content and, in the case of Macao, government approved advertisements, also apply.

F. Türkiye

Other countries such as Türkiye and those in the Middle East have regulatory review processes and data requirements for medicinal products, including vaccines, similar to those described for the European Union. The regulatory licensing process in these countries may include local marketing authorization requirements, manufacturing/testing facility inspections, testing of drug product upon importation and other domestic requirements. Some countries, such as Türkiye, have introduced specific emergency authorization regimes for COVID-19 vaccines.

G. Rest of the World Regulation

The requirements governing the conduct of clinical trials, product (including vaccine) licensing, pricing, and reimbursement vary from country to country in markets outside the European Union and the United States. In many markets, clinical trials must be conducted in accordance with Good Clinical Practice and applicable regulatory requirements. Ethical standards typically follow the Declaration of Helsinki principles. In response to the COVID-19 pandemic, some markets have granted or are considering the grant of emergency use authorizations for vaccine candidates instead of the otherwise available regulatory approval pathways. Supply of the COVID-19 vaccine to a number of countries outside of the United States and the European Union is similarly governed by vaccine supply agreements with local governments.

In Africa, there is limited harmonization of the regulation of drug and biological products across the continent, and the functionality and regulatory capacity of national medicines regulatory authorities varies between jurisdictions. For example, many regulators lack the technical expertise to independently assess marketing authorization applications and instead have adopted “reliance” procedures, whereby authorization by a foreign stringent regulatory authority or registration as a WHO pre-qualified product may be a condition for approval. The African Union (“AU”) has issued several harmonization initiatives for medicines, including establishing the AU Model Law on Medical Products Regulation in 2016 and the African Medicines Agency (“AMA”) in 2019. The AMA’s responsibilities will include evaluating medicines for the treatment of priority diseases, among other harmonization-related responsibilities, but has yet to issue any regulatory guidelines or procedures to date.

Failure to adhere to regulatory requirements may lead to, among others, fines, suspension or withdrawal of regulatory authorizations or approvals, product recalls, seizure of products, restrictions or suspensions of operations, or criminal prosecution.

H. Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Our current and future arrangements with providers, researchers, consultants, third-party payors and customers are subject to broadly applicable federal and state fraud and abuse, anti-kickback, false claims, transparency and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations in the United States and elsewhere include, without limitation, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in-cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or a specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the U.S. federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent or knowingly making, using, or causing to be made or used a false record or statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- HIPAA, which created additional U.S. federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or a specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as healthcare providers, health plans and healthcare clearinghouses and their respective business associates;
- the U.S. federal transparency requirements, known as the federal Physician Payments Sunshine Act, under the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- U.S. federal government price reporting laws, which require us to calculate and report complex pricing metrics to government programs and which may be used in the calculation of reimbursement and/or discounts on marketed products;
- the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);
- the national anti-bribery laws and laws governing interactions with healthcare professionals of European Union member states;
- the U.K. Bribery Act 2010; and
- analogous laws and regulations in U.S. states and other jurisdictions, such as U.S. state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some U.S. state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures and pricing information. Laws in U.S. states and other jurisdictions also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. U.S. federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Violations of these laws can subject us to criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties, and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our future operations and business.

I. Current and Future Healthcare Reform Legislation

In the United States and other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products. The Biden administration has discussed proposals to control drug pricing and new legislation may be proposed regarding government negotiation of drug pricing that may affect future profitability.

Additionally, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted:

- The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- The Middle Class Tax Relief and Job Creation Act of 2012 required that CMS reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting.

Further, there has been heightened governmental scrutiny in the United States and elsewhere over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the U.S. federal government, state legislatures, and other governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs to limit the growth of government-paid health care costs. For example, the U.S. federal government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation, from other countries and bulk purchasing.

J. Packaging and Distribution in the United States and Other Jurisdictions

If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply in the United States (and similar laws may apply in other jurisdictions). Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes, or the interpretation of existing regulations could impact our business in the future by requiring, for example, (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

K. Other Environmental, Health and Safety Laws and Regulations

In the United States, the European Union and other jurisdictions, we may be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation employers' liability insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

L. Regulation of Artificial Intelligence Systems and Models

Government authorities in the United States at the federal, state and local levels have been actively engaged in advancing policy frameworks, discussion papers, standards, and proposed legislation regarding the development and use of AI by life sciences companies and, where applicable, applying existing regulatory frameworks to particular uses of AI (e.g., by the FDA). Likewise, the EU and other countries and jurisdictions extensively regulate (or intend to extensively regulate) the development and use of AI systems and models. The processes for monitoring emerging regulatory frameworks, evaluating how current and emerging requirements for AI apply to our business, along with subsequent compliance with applicable requirements, require the expenditure of substantial time and financial resources.

A biotech company could use AI in a number of different contexts. It may use AI in the medicines lifecycle for drug discovery, for non-clinical research and development, for data analysis in clinical trials and with regard to real world data, for precision medicine (e.g., clinical decision support), for assessing eligibility for clinical trials, for drafting medicinal

product information documents, in the manufacturing of medicinal products, or to assist with post-authorization safety monitoring, among other potential uses. If the AI is intended to perform a regulated activity (such as related to drug manufacturing, release testing, or producing clinical/diagnostic outputs) or otherwise be used in operations that are the subject of scrutiny by health authorities, the use of AI could trigger health authority oversight and, in some cases, application of existing laws and regulations relevant to healthcare, pharmaceuticals, and/or medical devices or sector-agnostic AI laws and regulations.

Outside the drug development and commercialization context, a biotech company may use AI for other operational reasons. For example, a company may have plans to use automated recruitment tools, deploy facial recognition technology to ensure security of its services, use customer service chatbots, or allow its employees to use generative AI or general-purpose AI tools to increase the efficiencies of administrative tasks.

A company will need to identify how it uses AI in its business operations, and identify the relevant applicable regulatory regime that applies to ensure compliance. Failure to adhere to (or remain up to date with evolving) regulatory requirements may lead to compliance actions, penalties and other risks.

United States

In the United States, Congress, the White House, and various federal agencies have advanced proposed AI legislation, policy frameworks, whitepapers, and governing principles to address the use of AI, including when used in healthcare and life sciences. Of particular relevance to biotech companies, the FDA has been adapting and applying existing regulatory frameworks to account for AI and has issued guidance, discussion papers, and frameworks outlining FDA's approach to regulation and oversight of health-related uses of AI. For example, FDA issued two discussion papers on the use of AI in drug manufacturing (March 2023) and the development of drug and biological products (May 2023). The discussion papers described the various ways in which AI can be used throughout various stages of biopharmaceutical development and commercialization processes and solicited stakeholder feedback on several issues, including human-led governance and transparency, quality and reliability of data, AI model performance, validation, and monitoring, and where guidance from FDA would be beneficial for the industry. The discussion papers also recognized the potential utility of several existing "sector-agnostic" frameworks and standards, such as the AI Risk Management Framework issued by the National Institute of Standards and Technology and frameworks focused on AI-enabled medical devices. To date, FDA has been applying its existing regulations for drug and biologic discovery, development, clinical testing and manufacturing to companies utilizing AI in these processes, such that companies seeking to incorporate AI into processes that are subject to FDA oversight need to demonstrate compliance with the existing regulations for drug and biologic sponsors. FDA also actively regulates some health-related AI as "software as a medical device," or SaMD, and has issued a number of guidance documents and papers over the years describing FDA's regulatory approach to SaMD, including AI-based SaMD.

Additionally, in October 2023, the Biden Administration issued an Executive Order on the Safe, Secure, and Trustworthy Development of Artificial Intelligence, the AI Executive Order. The AI Executive Order contained a number of directives that may impact the life sciences sector, including directives to HHS to establish an AI "Task Force" responsible for issuing guidance on a number of AI topics (such as long-term safety and real-world performance monitoring, predictive and generative AI, equity principles, and privacy and security standards), develop a strategy for regulating the use of AI in drug development processes, develop an "AI assurance policy" to evaluate the performance of AI-enabled healthcare tools, and establish a common framework for capturing clinical errors resulting from AI deployed in healthcare settings. The AI Executive Order also sets forth certain reporting requirements for the development of certain AI models using primarily biological sequence data that meet outlined technical thresholds.

Members of Congress also have introduced a number of bills on AI regulation. In addition to proposed legislation, certain senators have released a proposed bipartisan framework for regulating AI that would, among other things, establish a licensing regime for certain types of higher-risk AI models, require transparency of essential information about training data, accuracy, limitations, and safety of the model, and mandate transparency with end users prior to their interaction with a model. Another senator likewise released a whitepaper about the oversight and legislative role of Congress related to the deployment of AI in the life sciences sector, which disfavored a "one-size-fits-all" approach to AI regulation and instead called for approaches that take context of use into account and leverage existing frameworks.

We continue to monitor developments in the regulation of AI in drug and biologic development and commercialization, or for more general business practices, and to assess the applicability of these evolving frameworks and policies as well as existing legal frameworks apply to our uses of AI. If we fail to meet regulator expectations or comply with applicable requirements, that could impact our ability to utilize AI-related processes or information in our development of product candidates or could subject us to delays, penalties or other risks.

European Union

The EU Artificial Intelligence Act, or the EU AI Act, which is scheduled for a final vote in the European Parliament in April 2024, will establish rules governing certain AI systems and general-purpose AI models that apply across the EU. It will apply to various actors along the AI value chain, including “providers” and “deployers” of AI systems classified as “high-risk,” “providers” of general-purpose AI models, and “providers” of general-purpose AI models with “systemic risk.” It also will prohibit certain AI practices and impose transparency requirements in relation to AI systems and general-purpose AI models generally.

The EU AI Act will apply to providers, located in or outside the EU, that place on the market or put into service AI systems in the EU, or that place on the market general-purpose AI models in the EU. It will also apply to deployers of AI systems located or established in the EU, and to providers or deployers located or established outside the EU where the output of the system is used in the EU. Whether a biotech company incurs obligations under the EU AI Act will depend on whether it develops, offers, or uses any AI systems or general-purpose AI models; whether it qualifies as a “provider,” “deployer,” or other regulated actor; and the jurisdiction where the system is put into service, where the system or model is placed on the market, or where the output of a system is used.

Providers and deployers of “high-risk AI systems” will need to comply with numerous obligations that apply to such systems. The obligations for providers and deployers differ, with the majority of obligations falling to providers. The EU AI Act also contemplates circumstances where a deployer or other third-party must assume the obligations of the provider, e.g., where the third-party makes a substantial modification to a high-risk AI system that has already been placed on the market or put into service, but where the modified system remains high risk. The EU AI Act sets out an exhaustive list of “high-risk AI systems” in Annexes II and III. The categories of such systems that might be relevant to offerings of biotech companies include products that require a notified body conformity assessment under the EU Medical Devices Regulation 2017/745 or EU *In Vitro* Diagnostic Medical Devices Regulation 2017/746.

The EU AI Act will impose a separate set of obligations on providers of “general-purpose AI models” and an additional set of obligations on providers of “general-purpose AI models with systemic risk.” Models that have “high-impact capabilities” will by default be designated as models with “systemic risk.” General-purpose AI models—with or without “systemic risk”—do not constitute “AI systems” in and of themselves, but they may be integrated into general-purpose AI systems, or systems with an intended purpose, including a high-risk purpose. Whether these obligations apply to a biotech company will depend on whether it develops any general-purpose AI models (or have them developed on its behalf) and place them on the market in the EU. If so, it will need to assess whether any of these models qualify as general-purpose AI models with systemic risk, which would require it to comply with additional obligations.

Of particular relevance to the biotech industry, the EMA has published a draft reflection paper on the use of AI (July 2023), which is aimed at biopharmaceutical companies intending to use AI in the lifecycle of their medicines, including for drug discovery, design, and development. It also covers the use of medical devices with AI/machine-learning (ML) technology that are used to generate data or other evidence to support an EU marketing authorization for a medicine (i.e., used within the context of clinical trials or combined with the use of a medicine). The EMA’s view of “high risk” AI differs from the classifications used in the EU AI Act and requires biotech companies to assess whether the use of AI is “high-risk” for the purpose of the EU medicines rules. This means determining whether there is a high-risk that it could impact or affect the integrity of data used to support an application for a medicine approval (and thus the EMA’s assessment of the safety and efficacy of that medicine for patients). As a result, potentially, non-high-risk AI under the EU AI Act could still be relevant to the EMA if it impacts evidence generation for a medicine. The EMA guidance puts the onus on marketing authorization applicants/marketing authorization holders to ensure AI used during the medicines lifecycle is compliant with the medicines rules. If a biotech company intends to use AI in the context of its medicines it will need to carry out a regulatory impact and risk analysis and potentially discuss higher risk uses with the EMA.

Failure to adhere to (or remain up to date with evolving) EU regulatory requirements may lead to delays, compliance risks, and penalties.

Rest of World

Outside the United States and EU, the requirements governing the use and deployment of AI may vary from country to country. A company will need to identify how it uses AI in its business operations, and identify the relevant applicable regulatory regime that applies to ensure compliance. Failure to adhere to (or remain up to date with evolving) regulatory requirements may lead to delays, compliance risks, and penalties.

XI. Intellectual Property

A. Introduction

We pursue a layered intellectual property strategy to protect our various technology platforms and their application to the treatment of serious diseases, such as cancer and infectious diseases including COVID-19. One focus of our intellectual property strategy is to provide protection for our platforms and products as they are developed. We also pursue intellectual property protection for assets that may be used in future development programs, may be of interest to our collaborators, and/or otherwise may prove valuable in the field.

Various aspects of our technology platforms and our product candidates are claimed in patent filings. We also pursue other modalities of intellectual property protection, including trademark and trade secret protection, as appropriate. Many of our intellectual property assets were developed and are owned solely by us, some have been developed via collaboration and are jointly owned, and some have been acquired by acquisition and/or licensed from third parties. We expect that we will continue to make additional patent application filings, and will continue to pursue opportunities to acquire and license additional intellectual property assets, technologies, platforms and/or product candidates, as developments arise or are identified.

Regardless, we cannot be certain that any of the patent filings or other intellectual property rights that we have pursued or obtained will provide protection for any products as commercialized. The original version of our *Comirnaty* COVID-19 vaccine product and our Omicron XBB.1.5-adapted monovalent COVID-19 vaccine have been approved, and our bivalent version (Original and Omicron BA.4/BA.5) has been authorized under Emergency Use Authorization (EUA) by the FDA in the United States for individuals 12 and older. In addition, both the original version of our *Comirnaty* COVID-19 vaccine product, our Omicron XBB.1.5-adapted monovalent COVID-19 vaccine, and our bivalent vaccine were also authorized by the FDA in the United States under EUA for individuals 6 months to <12 years old. As further variants of SARS-CoV-2 arise, and its impact and characteristics evolve, the composition, manufacture, and use (including, e.g., dosage regimen) of our COVID-19 vaccine products may be adjusted or modified and our filings may not protect them. Our other product candidates are currently in clinical testing, with no certainty that they will be successful, or that significant modification or adjustment may not be required for successful commercialization.

Our future commercial success depends, in part, on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents and other intellectual property; preserve the confidentiality of our trade secrets; and operate without infringing, misappropriating or violating the valid and enforceable patents and other intellectual property rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our products may depend on the extent to which we have rights under valid and enforceable patents, trade secrets or other intellectual property rights that cover these activities. With respect to both our owned and licensed intellectual property, we cannot be sure that patents will issue with respect to any of the owned or licensed pending patent applications or with respect to any patent applications that we, our co-owners or our licensors may file in the future, nor can we be sure that any of our owned or licensed patents or any patents that may be issued in the future to us or our licensors will be commercially useful in protecting any products that we ultimately attempt to commercialize or any method of making or using such products. Moreover, we may be unable to obtain patent protection for certain of our product candidates generally as well as with respect to certain indications. See “Risk Factors—Risks Related to our Intellectual Property” in this Annual Report on Form 20-F.

As of January 1, 2024, our overall owned and in-licensed patent portfolio included more than 350 patent families, each of which includes at least one filing in the United States or Europe, and several of which are pending or granted in multiple jurisdictions. The patent families include at least 200 patent families that are solely or jointly owned by BioNTech, including certain families acquired through our acquisitions and others that we have licensed from a third party.

An issued patent provides its owner (or possibly its licensee) with a right to exclude others from making, using or selling that which is claimed in the patent, for a specified period of time (the “term” of the patent), in the jurisdiction in which the patent is issued. In the United States, and in many other countries, patents have a presumptive term of 20 years from their effective filing date (which is the earliest non-provisional filing date to which the patent claims priority). However, many jurisdictions, including the United States, require the payment of periodic maintenance fees in order for patents to remain in force for the full 20-year term. The United States also has provisions that require a patent term to be shortened if its claims are too similar to another patent owned by the same party that has a shorter term. The United States and certain other jurisdictions also have provisions that permit extension of patent term for patents that claim a drug or drug product, or its approved use, if the patent was issued before clinical trials were completed and certain other requirements

were satisfied. In the United States, such extension is called a Patent Term Extension, or PTE, and it is limited to a period of not more than five years, or the total patent term including the PTE cannot exceed 14 years after the date of regulatory approval; only one patent can be extended per product approval. We did not extend any patent for our COVID-19 vaccine (*Comirnaty*) when it was approved by the FDA in the United States in 2021. The United States also offers a different form of patent term extension, known as Patent Term Adjustment, or PTA, whereby a particular patent's term is automatically extended beyond the 20-year date if the U.S. Patent and Trademark Office, or the USPTO, caused delay during its examination; however, potentially available PTA is reduced by any amount of any delay caused by the patent applicant.

Below, we provide a summary of the contours of our current patent portfolio as it relates to different aspects of relevant technology, including noting ownership and patent terms for filings included in the portfolio that are directed to such aspects. Particularly given our pre-commercial state of development for many product candidates, we cannot be certain that any of the patent filings in our portfolio will provide meaningful protection for products that we do or attempt to commercialize.

B. Patent Portfolio

The patent portfolios for our most advanced programs are summarized below. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted to the USPTO and similar authorities for examination can be significantly narrowed by the time they issue, if they issue at all. We expect this could be the case with respect to some of our pending patent applications referred to below.

1. mRNA

The patent portfolio for our mRNA therapeutic platforms and product candidates includes patent filings directed to features of therapeutic mRNA structures, some of which are included in our COVID-19 vaccine and in current development candidates. Our patent portfolio also includes patent filings directed to mRNA formulations (including their production and use), including the lipoplex formulations currently utilized with our *FixVac* and *iNeST* platforms, and the lipid nanoparticles currently utilized with our mRNA, *RiboMab* and *RiboCytokine* platforms, as well as patent filings directed to mRNA manufacturing, and to uses of mRNA therapeutics. We provide more detail below regarding the patent filings directed to these features.

mRNA Structure

Our patent portfolio includes patent filings directed to various features of mRNA structure, which may, for example, contribute to increased immunogenicity (e.g., antigen presentation), translation efficiency, and/or stability of mRNA constructs that include them. Such features include, for example, antigen-MHC fusions, 5' cap structures and related features, 3' UTR structures, polyA tails, reduced-uracil content mRNAs, and modified nucleoside RNAs. Filings directed to each of these features, and/or to RNA constructs that include them (singly or in combination), or collectively, the mRNA Structure Filings, have been made in the United States and various other jurisdictions. Some such mRNA Structure Filings are owned solely by BioNTech SE, which are referred to collectively in this section as BioNTech, some jointly by BioNTech and one or more third parties, and some by BioNTech licensors, such as Louisiana State University, or LSU, and the terms of the applicable agreement with LSU, are further summarized below in "C. In-Licensing." We have non-exclusive rights to use certain U.S. and European patent filings owned by University of Pennsylvania and relating to RNA containing modified nucleosides through our sublicense agreements with mRNA RiboTherapeutics, Inc. (MRT) and CellScript, LLC, collectively, the MRT-CellScript Sublicenses, and summarized below in "C. In-Licensing". Issued existing mRNA Structure Filings have, and pending existing mRNA Structure Filings, if issued, would have, 20-year terms that extend into the mid-2020s to the early-2040s.

mRNA Formulations

Our patent portfolio includes patent filings directed to various formulations for mRNA delivery, some of which are utilized with current development candidates. For example, our portfolio includes patent filings directed to lipoplex formulations and preparations thereof or collectively, the mRNA Lipoplex Filings. Issued mRNA Lipoplex Filing(s) has/have, and pending existing mRNA Lipoplex Filings, if issued, would have, 20-year terms that extend into the mid to late-2030s. Such mRNA Lipoplex Filings are solely owned by BioNTech or jointly owned by BioNTech and TRON.

In addition, our portfolio includes U.S. and other patent filings directed to lipid nanoparticles and polyplex technologies, which are solely owned by BioNTech or jointly owned by BioNTech and TRON, or collectively, the mRNA Lipid Nanoparticle/Polyplex Filings. Issued mRNA Lipid Nanoparticle/Polyplex Filings have, and pending mRNA Lipid Nanoparticle/Polyplex Filings, if issued, would have, 20 year terms that extend into the mid- to late 2030s or early 2040s. Some of such mRNA Lipid Nanoparticle/Polyplex Filings were granted in certain foreign jurisdictions, and currently include U.S. issued patents. The terms of the co-ownership of such patent filings with TRON are summarized below in “C. In-Licensing.”

mRNA Manufacturing

As discussed below, we utilize trade secret protection for many aspects of our mRNA manufacturing technologies, including as currently utilized for production of certain of our development candidates. In addition, our patent portfolio includes certain patent filings relevant to mRNA manufacturing, or collectively, the mRNA Manufacturing Filings, which we believe may provide commercial value to protect product candidates and/or support collaborations or other licensing arrangements. For example, our mRNA Manufacturing Filings include U.S. and other patent filings relating to certain aspects of mRNA purification and production. These mRNA Manufacturing Filings are either solely owned by BioNTech, or jointly owned by BioNTech and TRON and, if issued, would have 20-year terms that would extend into mid 2030 to early 2040s; there are patents granted in certain foreign jurisdictions including EP, but no U.S. patent was yet issued.

mRNA Commercial Products and Product Candidates

Our COVID-19 vaccine. Our COVID-19 vaccine (BNT162b2), marketed as *Comirnaty*, is our most advanced mRNA product, and is sold in monovalent (based on the Original strain as well as on the Omicron XBB.1.5 variant) and bivalent (one RNA based on the Original strain and one RNA based on an Omicron variant) formats. The monovalent format (Original and Omicron XBB.1.5) has received full U.S. FDA approval for individuals 12 and older and Emergency Use Authorization (EUA) for individuals 6 months to <12 years old, as well as full and/or conditional marketing approval in various other jurisdictions. The bivalent format (Original and Omicron BA.4/BA.5) has been authorized under EUA by the FDA in the United States for individuals 6 months and older. In Europe, two bivalent versions (Original and Omicron BA.1; and Original and Omicron BA.4/BA.5) have received marketing authorization for individuals 12 years and older. Additional COVID-19 vaccine candidates, as well as various dosing regimens and use in patient populations with certain medical conditions are being tested in clinical trials.

Comirnaty and Other COVID-19 Vaccine mRNA Product Candidates

Both our current and previously-marketed monovalent and bivalent COVID-19 vaccines utilize modified-nucleoside mRNA formulated in lipid nanoparticles and which encode an optimized SARS-CoV-2 full-length spike protein antigen.

Our platform patent filings relevant to our COVID-19 vaccines, collectively, the “BNT162b2 Platform Filings”, include certain mRNA Structure Filings relating to features for increasing translation efficiency and/or stability of mRNA constructs (e.g., certain 3' UTR structures containing a specific sequence element, interrupted polyA tails, and certain 5' cap/cap proximal sequence combinations), including filings that are jointly owned by BioNTech and TRON; also relevant are certain mRNA Manufacturing Filings. Issued BNT162b2 Platform Filings have, and pending BNT162b2 Platform Filings, if issued, would have 20-year terms extending into the late-2020s to the early-2040s. We also have undertaken various patent filings specifically related to the BNT162b2 structure (including as may be tailored based on particular SARS-CoV-2 variants), composition, formulation, packaging, use and/or manufacture, collectively the BNT162b2 Filings, including filings that have arisen through collaboration with third parties such as Pfizer. Such filings relevant to our COVID-19 vaccines, if issued, would have 20-year terms that would extend into early 2040s; there is one issued U.S. patent and one allowed U.S. patent application within the BNT162b2 Filings that covers our COVID-19 vaccines.

As noted above, our MRT-CellScript Sublicenses grant us rights to use certain U.S. and European patents and applications relating to mRNA containing modified nucleosides, including as used in BNT162b2. We also have a non-exclusive license from the National Institutes of Health granting us a right to use certain technology described in U.S. and European patent filings that may relate to SARS-CoV-2 spike (S) protein mutations that lock the S protein in an antigenically preferred prefusion conformation; such a variant is utilized in BNT162b2.

Additionally, we have obtained third-party licenses to technologies relating to certain lipids and/or lipid nanoparticles and formulations used in BNT162b2, including a non-exclusive license from Acuitas Therapeutics Inc., or Acuitas, granting use rights relevant to proprietary lipid nanoparticles and formulations used in BNT162b2.

Additional COVID-19 vaccine mRNA product candidates are being developed and tested in clinical trials, which share with BNT162b2 certain structural elements, and/or features of the composition, formulation, packaging, use and/or method of manufacture. Thus, some or all of the BNT162b2 Platform Filings and/or BNT162b2 Filings, as well as the in-licensed rights discussed above with respect to BNT162b2, may be relevant to certain of these candidates. We have also undertaken patent filings specifically related to structures and uses of certain such additional candidates, including BNT162b4, which includes a T-cell antigen mRNA encoding SARS-CoV-2 non-spike protein antigens that are highly conserved across a broad range of SARS-CoV-2 variants and were chosen based on our proprietary target prioritization platform and which is being assessed in combination with our monovalent and bivalent COVID-19 vaccine products, and BNT162b5, a bivalent product that includes RNAs encoding enhanced prefusion spike proteins for the SARS-CoV-2 Original strain and an Omicron variant. Such filings specifically relevant to BNT162b4 or BNT162b5, if issued, would have 20-year terms that would extend into the early 2040s.

Moreover, we are currently studying safety and efficacy of our COVID-19 vaccines and vaccine candidates in various dosing regimens (including booster doses) and/or in different age groups and/or individuals with various medical conditions, and also in combination with other vaccines or therapies. Certain of our patent filings, including certain BNT162b2 Filings, cover such uses being tested in clinical trials.

Oncology mRNA Product Candidates

Certain mRNA oncology product candidates are also in clinical development and involve various platforms. Our pipeline also includes mRNA product candidates for treatment of certain infectious diseases beyond COVID-19, and mRNA product candidates for protein replacement therapy in certain rare diseases. We currently have more than 10 clinical oncology programs in Phase 1 or Phase 2. Our most advanced clinical oncology programs involve our iNeST immunotherapy product candidates being developed with our collaborator, Genentech. We also have *FixVac* product candidates in Phase 1 and Phase 2 clinical trials and have initiated Phase 1 clinical trials of our mRNA-based intratumoral immunotherapy developed through our collaboration with Sanofi.

FixVac

Our *FixVac* product candidates share many of the structural elements involved in our iNeST product candidates. Thus, some or all of the mRNA Structure Filings relevant to our iNeST product candidates and discussed below are also relevant to our *FixVac* product candidates. These patent filings, or the *FixVac* Platform Filings, include mRNA Structure Filings relating to antigen-MHC fusions, certain 5' cap structures, 3' UTR structures containing a specific sequence element, and interrupted polyA tails, which are solely or jointly owned by BioNTech or BioNTech's licensors. Issued *FixVac* Platform Filings have, and pending *FixVac* Platform Filings, if issued, would have, 20-year terms extending into the mid-2020s to the mid-2030s. While we have pursued or obtained patent protection covering components of *FixVac* product candidates, manufacturing-related methods and/or formulations, we do not currently have any claims in our owned or in-licensed issued patents that cover the overall construct used in our *FixVac* product candidates.

Our patent portfolio further includes U.S. and other patent filings relating to combined uses of our *FixVac* and iNeST product candidates. Such issued patent filings have, and such pending patent filings, if issued, would have, 20-year terms that extend into 2033, and are jointly owned by BioNTech and TRON.

Our current clinical trials for *FixVac* product candidates are studying such product candidates in treatment of various cancers. While we do not currently have any claims in our owned or in-licensed issued patents that are directed to use of our *FixVac* product candidates in the indications of these clinical trials, certain *FixVac* Platform Filings include specific reference to treatment of these indications, and if issued, would have 20-year terms extending into the mid-2030s.

iNeST

Our patent filings relevant to our iNeST product candidates include mRNA Structure Filings relating to features for increasing antigen presentation (e.g., antigen-MHC fusions) and features for increasing translation efficiency and/or stability of mRNA constructs (e.g., certain 5' cap structures, 3' UTR structures containing a specific sequence element, and

polyA tails of a particular length or interrupted polyA tails); mRNA Lipoplex Filings relating to negatively charged lipoplexes (*e.g.*, for spleen targeting); and mRNA Manufacturing Filings, or collectively, the iNeST mRNA Platform Filings. While we have pursued or obtained patent protection covering components of iNeST product candidates, manufacturing-related methods and/or formulations, we do not currently have any claims in our owned or in-licensed issued patents that cover the overall construct used in our iNeST product candidates.

Our patent portfolio further includes U.S. and other filings directed to the process of identifying neoantigens in patient samples and/or predicting those that will be immunoreactive in an iNeST immunotherapy product, or collectively, the Neoantigen Filings. Certain issued Neoantigen Filings have, and certain pending Neoantigen Filings, if issued, would have 20-year terms that extend into the 2030s. Many of the Neoantigen Filings are solely owned by BioNTech, or jointly owned by BioNTech and TRON; our acquisition of Neon added various Neoantigen Filings, including both BioNTech U.S.-owned and in-licensed filings. BioNTech and TRON jointly own issued EP patent number 2714071, whose claims recite steps relating to neoantigen selection, that were unsuccessfully opposed by multiple third parties; said third parties have appealed the decision to reject such opposition. In addition, related EP patent numbers 3473267 and 3892295 from the same patent family with claims reciting steps relating to neoantigen selection for an RNA vaccine encoding a recombinant polyepitopic polypeptide are being opposed by a third party; claims in the related U.S. case are granted. If we are unsuccessful in these opposition/appeal proceedings, the patent claims for our iNeST product candidates may be narrowed, or a patent may not issue at all. See “Risk Factors—Risks Related to our Intellectual Property” in this Annual Report on Form 20-F.

We are currently studying our iNeST product candidates for the treatment of metastatic melanoma and pancreatic cancer in Phase 2 clinical trials and those for the treatment of various solid tumors in Phase 1 clinical trials. Certain iNeST mRNA Platform Filings and Neoantigen Filings cover treatment of each of these indications. However, we do not currently have any claims in our owned or in-licensed issued patents that are directed to use of iNeST product candidates in the indications of these clinical trials.

Intratumoral Immunotherapies

Certain of the mRNA Structure Filings (including some that are relevant to iNeST and/or *FixVac* product candidates, as discussed above) are also directed to one or more features of our intratumoral immunotherapies, including our most advanced intratumoral immunotherapy, which we are developing through our collaboration with Sanofi, and which has entered Phase 1 clinical trials. For example, mRNA Structure Filings relating to 3' UTR structures containing a specific sequence element, and interrupted polyA tail structures, which, as noted above are solely or jointly owned by BioNTech, provide protection to our current intratumoral immunotherapy development candidate. Such issued patent filing(s) has/have, and such pending patent filings, if issued, would have, 20-year terms that extend into the mid-2030s.

Certain patent filings that are relevant to intratumoral immunotherapies include certain patent filings under the MRT-CellScript Sublicenses, which include patent filings directed to nucleotide-modified mRNAs.

Additionally, certain patent filings have arisen from our collaboration relating to compositions including mRNAs encoding particular cytokines for treatment of solid tumors, or the mRNA Cytokine Filings. Such mRNA Cytokine Filings, if issued, would have 20-year terms that would extend into 2038. We have assigned certain of such mRNA Cytokine Filings (including one issued foreign patent) to Sanofi in accordance with our agreement.

RiboMabs and RiboCytokines

We own or license a number of patent filings directed to our *RiboMab* and *RiboCytokine* programs. Many are owned solely by us, some are jointly owned, and some have been acquired or licensed.

Patent filings relevant to our *RiboMab* and *RiboCytokine* programs include certain mRNA Structure Filings that are also relevant to our iNeST and/or *FixVac* product candidates, including certain patent filings relating to 3' UTR structures containing a specific sequence element, and interrupted polyA tail structures; and patent filings under the MRT-CellScript Sublicenses relating to nucleoside-modified mRNAs as well as certain patent filings we have licensed from Acuitas and Genevart relating to lipid or non-liposomal formulations.

Infectious Diseases beyond COVID-19

As is discussed elsewhere, we have collaborated with third parties, including Pfizer and the University of Pennsylvania, to develop infectious disease mRNA vaccine candidates, some of which are currently in clinical trials at different phases, including mRNA vaccines against influenza (Phase 3) and HSV (Phase 1). We are also developing our own mRNA vaccines against malaria, which has recently entered Phase 1 clinical trial.

Certain patent filings that might be useful to our infectious disease mRNA vaccines include certain of the mRNA Structure Filings and the mRNA Lipid Nanoparticle/Polyplex Filings as well as certain patent filings under the MRT-CellScript Sublicenses, which include patent filings directed to nucleotide-modified mRNAs. Self-Amplifying RNA Filings as discussed above may also be relevant. We have also undertaken and continue to undertake filings specific to particular product candidates.

We have also licensed technologies relating to certain lipids and/or lipid nanoparticles and formulations that may be useful for certain infectious disease mRNA vaccines.

Rare Diseases

We are developing mRNA-based protein replacement therapy for several rare disease indications through our collaboration with Genevant.

Certain of the mRNA Structure Filings (including some that are relevant to iNeST and/or *FixVac* product candidates, as discussed above) and patent filings under the MRT-CellScript Sublicenses (including patent filings directed to nucleoside-modified mRNAs) also provide protection for one or more features of mRNA-based protein replacement product candidates. For example, mRNA Structure Filings include patent filings directed to 3' UTR structures containing a specific sequence element and interrupted poly A tail structures. As noted above, such mRNA Structure Filings are solely or jointly owned by BioNTech; such issued patent filing(s) has/have, and such pending patent filings, if issued, would have 20-year terms that would extend into the mid-2030s. However, there are currently no issued patents specific to our rare disease product candidates under development.

Our patent portfolio relating to our rare disease programs also include certain patent filings that we have licensed from Genevant, or the Genevant Filings. Specifically, some of the Genevant Filings are owned by Arbutus Biopharma Corporation and relate primarily to lipid or non-liposomal formulations that might be useful in these programs, with 20-year terms that extend into mid-2020s to mid-2030s for the issued Genevant Filings and the pending Genevant Filings, if issued.

2. Cell Therapy

Engineered Cell Therapy

Our engineered cell therapy product class features use of chimeric antigen receptor, or CAR-, T cell or individualized T-cell receptors for oncology therapy. Our patent filings relevant to these platforms and product candidates, or the CAR-T/TCR Filings, are generally co-owned by BioNTech US, BioNTech Cell & Gene Therapies and TRON. For example, the CAR-T/TCR Filings include patent filings directed to various CAR-T formats and methods of enhancing CAR-T cells by nucleic acid vaccination, as well as patent filings directed to compositions of matter comprising individualized T-cell receptors, for example. The CAR-T/TCR Patent Filings, if issued, would have patent terms that would extend into the mid-2030s to early 2040s.

Certain CAR-T programs involve CAR-T-cell product candidates that target different members of the claudin family. Our patent portfolio includes certain patent filings specifically relevant to our claudin-specific CAR-T-cell product candidates and are jointly owned by BioNTech Cell & Gene Therapies, and TRON, or the Claudin-Specific CAR-T Cell Filings. The issued Claudin-Specific CAR-T-cell filings have, and the pending Claudin-Specific CAR-T-cell filings, if issued, would have, 20-year terms extending into the mid-2030s. The terms of our co-ownership of such patent filings with TRON are summarized below in “—C. In-Licensing.”

Activated T Cells

Our acquisition of Neon included technologies for using peripheral blood mononuclear cells, or PBMCs, (e.g., collected from apheresis material of patients) as a starting material to induce and/or expand ex vivo functional T cells specific for therapeutically-relevant neoantigens.

Our BNT221 program, formerly Neon's NEO-PTC-01 program, is a personalized adoptive T-cell therapy, which uses multiple T-cell populations expanded from an individual patient's PBMCs that together target a set of neoantigens expressed by that patient's tumor.

Patent filings relevant to BNT221, referred to herein as the T-cell Induction/Expansion Filings, are generally solely owned by BioNTech US, or co-owned by BioNTech US and the Netherlands Cancer Institute (NKI). For example, the T Cell Induction/Expansion Filings include patent filings directed to therapeutic T cell compositions and methods of ex vivo induction and/or expansion of antigen-specific T cells. An issued subsisting T-cell Induction/Expansion Filing in the United States has, and pending subsisting T-cell Induction/Expansion Filings, if issued, would have, patent terms that extend into the late-2030s to early-2040s.

3. Antibodies

Our antibodies product class features bispecific checkpoint immunomodulators for oncology therapy, which are developed through collaboration with Genmab. Our development candidates include bispecific antibodies that are designed to activate 4-1BB upon simultaneous binding to PD-L1, CD-40 or EpCAM. Our patent portfolio includes certain patent filings relevant to such bispecific antibodies, or the Bispecific Checkpoint Modulator Filings, co-owned by us and Genmab. Such Bispecific Checkpoint Modulator Filings, if issued, would have 20-year terms that would extend into the late 2030s.

We have also recently expanded our collaboration with Genmab to include development of monospecific antibody candidates to address malignant solid tumors. For example, BNT313 is a CD27 antibody based on Genmab's proprietary HexaBody technology platform, specifically engineered to form an antibody hexamer (a formation of six antibodies) upon binding its target on the cell membrane of the T cells. We have also undertaken and continue to undertake filings specific to particular product candidates.

We own patent assets acquired from MabVax Therapeutics Holding, Inc., or the MabVax Filings, that relate to various antibodies, including certain antibodies targeting sialyl Lewis A and ganglioside GD2, as well as nucleic acid encoding them. Issued MabVax Filings have, and the pending MabVax Filings, if issued, would have, 20-year terms that extend into the mid-2030s.

4. Small Molecule Immunomodulators

Our small molecule therapeutics product class features oncology treatment using small molecule product candidates that activate the immune system via TLR7 agonism. Our patent portfolio includes patent filings relevant to these TLR7 agonists, or the TLR7 Agonist Filings. Certain TLR7 Agonist Filings are directed to substituted imidazoquinolines, and, if issued, would have 20-year terms that would extend into the late 2030s.

C. In-Licensing

Some of our intellectual property assets have been acquired by acquisition and/or in-licensing.

We have pursued a strategy of identifying and in-licensing third-party patents that we believe are complementary to or otherwise interact synergistically with our own intellectual property portfolio. In addition to the agreements described in the section "—B.IX. Third-Party Collaborations" above, we have entered into material intellectual property licensing or option arrangements with TRON, Louisiana State University, MRT-CellScript, and Acuitas.

The key terms of these arrangements are summarized below.

TRON Agreements

In 2015, we and our subsidiaries BioNTech RNA (now merged into BioNTech SE), BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, Eufets GmbH and JPT Peptide Technologies GmbH entered into a Master Agreement for Research Services with TRON. Concurrently with this Master Agreement for Research Services, or the TRON Research Agreement, we entered into a License Agreement with Ganymed

Pharmaceuticals AG, or Ganymed, TRON, Johannes Gutenberg-Universität Mainz and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, or the TRON License Agreement. The TRON Research Agreement and TRON License Agreement together replaced and superseded our 2008 Cooperation, Purchase and Licensing Agreement with the University Mainz, or the 2008 Cooperation Agreement. In 2019, we and our subsidiaries BioNTech RNA (now merged into BioNTech SE), BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, BioNTech Innovative Manufacturing Services GmbH and JPT Peptide Technologies GmbH, entered into a Framework Collaboration Agreement with TRON, or the TRON Collaboration Agreement.

TRON Research Agreement

Under the TRON Research Agreement, TRON from time to time performs certain services for us under work orders, which may comprise innovative applied research projects, pre-defined research and development or clinical research services. We and TRON meet at regular intervals, but no less than annually, to prepare an overall non-binding project plan, which sets the scope, period and costs for the relevant projects contemplated for that period. Individual work orders set the specific binding terms of each project or service. TRON is obligated to render services in accordance with the scientific standards, all applicable laboratory and legal provisions and with the care customary in the industry.

We are entitled to the exclusive rights to all inventions, methods, specifications, materials, documents, data, know-how and other results (together, the Results) developed or discovered by TRON or by us and TRON jointly under the TRON Research Agreement, except to the extent they constitute improvements of the technologies applied by TRON in the relevant projects. Under the TRON Research Agreement, TRON granted us a non-exclusive, royalty-free license to use TRON Improvements if such TRON Improvements are necessary for the continued development and exploitation of the Results or the manufacture or marketing of products which contain any of the Results and are covered by a patent claiming any of the Results.

Under the TRON Research Agreement, TRON's services rendered in the field of applied research are invoiced at cost. For other services, fixed prices are to be set forth in the individual work orders. TRON invoices us monthly and our payments are due no later than 10 days thereafter. Additionally, we are obligated to pay to TRON low single-digit tiered royalties on net sales of any product developed under the TRON Research Agreement that is covered by a patent claiming any of the Results.

The TRON Research Agreement limits each party's liability to the other to intentional and grossly negligent actions and, in the case of gross negligence, liability for indirect and consequential damages and lost profits is excluded. We are obligated to indemnify TRON for all product liability claims in connection with the products and for third-party claims asserting that the Results violate third-party intellectual property rights.

The TRON Research Agreement has an indefinite term, but may be terminated by either party on six months' notice. If one of our subsidiaries terminates its role in the TRON Research Agreement, the agreement will survive and continue without that subsidiary.

In November 2017, we and TRON entered into a supplementary agreement to include certain research and development activities regarding neoepitope RNA immunotherapies as work included in the TRON Research Agreement. In February 2022, we agreed to extend the term of the supplementary agreement.

TRON License Agreement

The TRON License Agreement governs the ownership of and licenses under certain patents, inventions, know-how, technologies and other knowledge (together, the Development Results) filed and created before January 1, 2015 in the course of our collaboration with TRON, Johannes Gutenberg-Universität Mainz and Universitätsmedizin der Johannes Gutenberg-Universität Mainz (collectively, the University Parties) and Ganymed pursuant to the 2008 Cooperation Agreement.

The TRON License Agreement sets forth the parties' rights with respect to the Development Results, mainly depending on which parties have contributed to such Development Results. Ownership of the Development Results and any patents and other intellectual property in certain shares to TRON, on the one hand, and BioNTech and/or Ganymed, on the other hand included therein is allocated. Each party may assign its share in the co-owned Development Results to its affiliates provided that such party provide notice of the transfer and the identity of the new co-owner to the other co-

owners. However, in case of an assignment of such share to a third party (except in case of a material asset sale), the assigning party must obligate the assignee to comply with the terms of the TRON License Agreement and the assigning party will remain bound by the obligations of the TRON License Agreement unless the other co-owners have consented to discharge the assigning party from such obligations.

The parties to the TRON License Agreement grant licenses to each other under their shares in the Development Results substantially as follows. Ganymed is exclusively entitled to use the Development Results for certain antibodies and antibody fragments that bind to certain defined targets, or the Ganymed Field of Use. We are exclusively entitled to use the Development Results in any other field of use (including immunological therapeutics, small molecule compounds, small interfering RNA (siRNA)-based therapeutics, micro-proteins, antibody based *in vitro* (except for those in the Ganymed Field of Use), diagnostics and therapeutics based on long-chain RNA as well as other cell therapy applications, immune cells transgenized with recombinant directed against certain defined targets or chimeric antigen receptors and RNA-based pharmaceuticals). The University Parties may use the Development Results for internal research purposes only. We have an obligation to use reasonable efforts to develop and commercialize products in our field of use worldwide.

Under the TRON License Agreement, we and Ganymed must agree on which party will have the primary role in filing, prosecuting, maintaining and defending jointly owned patents. We and Ganymed each have the exclusive right to enforce the Development Results in our respective fields of use, subject to certain step-in rights of the other parties.

We are obligated to pay to the University Parties low single-digit tiered royalties on net sales on any product that is covered by certain of the patents including in the Development Results. If licenses are granted to third parties, we are obligated to pay to the University Parties a mid-single-digit share of all upfront payments, milestone payments and other remuneration we receive from such third parties in consideration for the license. Regarding upfront payments only, the University Parties' share will be offset against subsequent license fees on net sales. In addition, we are obligated to pay certain development and regulatory milestones up to a low seven-figure amount to Johannes Gutenberg-Universität Mainz.

The TRON License Agreement contains a limitation on liability as between the parties, wherein the parties will only be liable to each other for intentional and grossly negligent actions, and, in the case of gross negligence, liability for indirect and consequential damages and lost profits is excluded. We are obligated to indemnify the University Parties and Ganymed for third-party claims of product liability or violation of applicable law based on our distribution of our products or if we breach the TRON License Agreement or if we or one of our agents acts culpably.

The TRON License Agreement will remain in effect as long as there are any obligations on us or Ganymed to pay license fees. After expiry of the TRON License Agreement, each party will have a perpetual, non-exclusive, royalty-free license to use the Developments Results. The TRON License Agreement may be terminated by any party on six months' notice. The licenses granted between the parties will survive such termination. The TRON License Agreement also grants all parties termination rights for uncured material breaches. If only one party terminates its role in the Agreement, the Agreement will survive and continue between the other parties.

TRON Collaboration Agreement

Under the TRON Collaboration Agreement, TRON from time to time undertakes certain projects in collaboration with us under separate project specific agreements, comprising innovative non-clinical research and development projects. We and TRON meet regularly to review and update project plans, and no less than annually to agree the budget for the on-going projects for the coming calendar year. Individual project agreements set the specific binding terms of each project. TRON is obligated to perform its obligations in accordance with the scientific standards, all applicable technical laboratory and legal provisions and with the care customary in the non-clinical biotechnology research industry.

Except for the results of a particular research project which has been funded exclusively by TRON, or the RNT Project, all of the inventions, methods, specifications, materials, documents, data, know-how and other results (together, the Results) developed or discovered by TRON or by us and TRON jointly under the TRON Collaboration Agreement are jointly owned. The Results of the RNT Project are owned exclusively by TRON. Under the TRON Collaboration Agreement, TRON grants us an exclusive, worldwide, sublicensable license under its interest in the Results to research and have researched, develop and have developed, make and have made, use, and otherwise commercialize or have commercialized, and otherwise commercially exploit, products in a field that is specified in the corresponding project agreement. The field of use is either (a) the prophylaxis, diagnosis and treatment of all indications in humans and animals; (b) the prophylaxis, diagnosis and treatment of oncological diseases, infectious diseases and rare genetic diseases; or (c) in

the case of the Results from the RNT Project only, the prophylaxis, diagnosis and treatment of rectal neuroendocrine tumors in humans. We are required to use our reasonable efforts to develop and commercialize products that exploit the Results.

Under the TRON Collaboration Agreement, TRON's activities are invoiced at cost. TRON invoices us monthly and our payments are due no later than 10 days thereafter. Additionally, we are obligated to pay to TRON low single-digit tiered royalties on net sales of any product developed under the TRON Collaboration Agreement that is covered by a patent claiming any of the Results or, in certain circumstances, by a patentable invention forming part of the Results which we elect to maintain as a trade secret. If licenses under Results are granted to third parties, we are obligated to pay to TRON a mid-single-digit share of all upfront payments, milestone payments and other remuneration we receive from such third parties in consideration for the license. In addition, we are obligated to pay a one-time only milestone of a low seven-figure amount to TRON the first time annual sales of a product developed under the TRON Collaboration Agreement reach a low nine-figure number.

The TRON Collaboration Agreement limits each party's liability to the other to cases of willful misconduct and gross negligence and, in the case of gross negligence, liability for indirect and consequential damages and lost profits is excluded. We are obligated to indemnify TRON for all product liability claims in connection with the products and for third-party claims asserting that the Results violate third-party intellectual property rights.

The TRON Collaboration Agreement came into force with retroactive effect from January 2015 and has an indefinite term, but may be terminated by either party on nine months' notice. If one of our subsidiaries terminates its role in the TRON Collaboration Agreement, the agreement will survive and continue without that subsidiary.

LSU License Agreement

In May 2015, we entered into a Patent License Agreement with the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College, or LSU, and the University of Warsaw, or UW. The agreement (which we refer to as the LSU Agreement) replaces and supersedes the earlier license agreement between the parties.

Under the LSU Agreement, UW and LSU granted to us an exclusive royalty-bearing license under certain patent rights relating to mRNA cap analogs and the synthesis and use of anti-reverse phosphorothioate analogs of the mRNA cap in the United States, certain jurisdictions in the European Union and other countries. As consideration for the license granted, we are obligated to pay running royalties in the low single digits on all net sales of products utilizing the licensed patents and to pay annual maintenance fees to LSU.

We are obligated to use commercially reasonable efforts to develop one or more marketable products utilizing the licensed patents, upon which we would owe additional milestone payments to LSU.

The LSU Agreement remains in effect until expiration of the licensed patents. We have the right to terminate the LSU Agreement for convenience with 60 days' prior notice, and LSU and UW may terminate for our uncured material breach.

CellScript and mRNA Ribotherapeutics License Agreement

BioNTech RNA (now merged into BioNTech SE) entered into the two MRT-CellScript Sublicenses discussed above. Together, the MRT-CellScript Sublicenses grant BioNTech RNA worldwide, non-exclusive sublicenses under the Penn Modified mRNA Patent Rights (as defined in the MRT-CellScript Sublicenses) to research, develop, make, import, use and commercialize products for in vivo uses in humans and non-human animals, including therapeutic and prophylactic applications, and for certain uses in the diagnostic and prognostic field of use and certain laboratory research or screening uses. Under these sublicenses, BioNTech RNA has the right to grant sublicenses to affiliates and third parties.

BioNTech RNA must use reasonable efforts to develop and commercialize products under the sublicenses. Furthermore, BioNTech RNA is obliged to pay MRT and CellScript development milestone payments of up to approximately \$26 million as well as royalties in the low to mid-single digits on net sales of licensed products, depending on the field of use.

The agreements continue until the expiration or abandonment of the last licensed patent to expire or be abandoned. BioNTech RNA may terminate the agreement for convenience with respect to all or certain patent rights with 60 days' prior

written notice. MRT or CellScript may terminate the respective sublicense agreement for payment default, uncured material breach or the bankruptcy of BioNTech RNA.

Acuitas License Agreement

In April 2020 we entered into a Non-Exclusive License Agreement with Acuitas, or the Acuitas License Agreement. Under the Acuitas License Agreement Acuitas grants us a non-exclusive worldwide license, with the right to sublicense (subject to certain conditions) under Acuitas's LNP technology to develop, manufacture and commercialize licensed products directed to the SARS-CoV-2 surface glycoprotein. We have the option to convert the non-exclusive licenses to exclusive licenses subject to certain additional financial obligations.

Under the Acuitas License Agreement, we must pay Acuitas up to between approximately \$1.6 million and \$2.45 million in development milestone payments, \$2.5 million and \$3.75 million in regulatory milestone payments and \$2.5 million and \$3.75 million in commercial milestone payments upon the occurrence of certain milestone events. We are further required to pay Acuitas a low single-digit tiered percentage royalty on net sales of licensed products, subject to certain potential customary reductions. Our royalty obligations continue under the Acuitas License Agreement on a country-by-country and product-by-product basis until the later of (i) the expiration of the last-to-expire licensed valid patent claim covering such licensed product in such country, (ii) expiration of any data exclusivity, market exclusivity or supplemental protection certificates period for such product in such country, and (iii) certain years following the first commercial sale of such product in such country.

The Acuitas License Agreement will continue on a product-by-product and a country-by-country basis until there are no more payments owed to Acuitas for such product in such country. Upon expiration of the Acuitas License Agreement, the license will become fully paid up and will remain in effect. We have the right to terminate the Acuitas License Agreement for convenience following a certain notice period. Either party may terminate the Acuitas License Agreement in the event of a material breach by the other party following a cure period. Alternatively, instead of exercising our right to terminate in the event of Acuitas's material breach, we may elect to instead continue the license but reduce our milestone and royalty payment obligations to Acuitas by a certain percentage. In the event of termination of an Acuitas License Agreement by us for convenience or by Acuitas for our material breach, the licenses granted under such agreement will terminate, except that we will have the right to sell off any remaining inventories of licensed products for a certain period of time.

D. Trademark Portfolio

Certain features of our business and our product candidates are protected by trademarks. Our trademark portfolio includes, but is not limited to, *Comirnaty*, *BioNTainer*, *FixVac*, *RiboCytokine*, *RiboMab*, *Recon*, and *Neo-Stim*, including logo versions of some of these trademarks.

Brand names appearing in italics throughout this report are trademarks owned by BioNTech. All other trademarks are the property of their respective owners.

E. Trade Secret Protection

Certain of our technologies, including in particular certain proprietary manufacturing processes or technologies and/or neoantigen prediction technologies, are protected as trade secrets.

In addition to patent protection, we rely upon unpatented trade secrets and confidential know-how and continuing technological innovation to develop and maintain our competitive position. We protect certain of our technologies, including, in particular, certain proprietary manufacturing processes and technologies and/or neoantigen prediction technologies, as trade secrets. However, trade secrets and confidential know-how are difficult to protect. We seek to protect our proprietary information, in part, by using confidentiality agreements with any future collaborators, scientific advisors, employees and consultants, and invention assignment agreements with our employees. We also have agreements requiring assignment of inventions with selected consultants, scientific advisors and collaborators. These agreements may not provide meaningful protection. These agreements may also be breached, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and/or confidential know-how may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain or use information that we regard as proprietary. Although we take steps to protect our proprietary information, third parties may

independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information.

XII. Competition

We compete in an industry characterized by rapidly advancing technologies, intense competition and a complex intellectual property landscape. We face substantial competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions.

Many of our competitors and potential competitors, either alone or with their collaborators, have greater scientific, research and product development capabilities as well as greater financial, marketing, sales and human resources and experience than we do. In addition, smaller or early-stage companies, including immunotherapy-focused therapeutics companies, may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Some of our collaborators, such as Genmab, Pfizer and Sanofi, may also be competitors within the same market or other markets. Accordingly, our competitors may be more successful than us in developing and potentially commercializing technologies and achieving widespread market acceptance. In addition, our competitors may design technologies that are more efficacious, safer or more effectively marketed than ours or have fewer side effects, or may obtain regulatory approvals more quickly than we are able, which could eliminate or reduce our commercial potential. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We anticipate that the key competitive factors affecting our technologies will be efficacy, safety, cost and convenience, ease of distribution, storage and administration, as well as our ability to build a fully-integrated biotechnology company. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. The timing of market introduction of our products and competitive products will also affect competition among products. We expect the relative speed with which we can develop our products, complete the clinical trials and approval processes, and supply commercial quantities of the products to the market to be important competitive factors. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Specifically, our marketed monovalent and bivalent COVID-19 vaccines and any other COVID-19 vaccines we and Pfizer develop compete with other COVID-19 vaccines that have been approved or authorized for temporary or emergency use and a large number of vaccine manufacturers, academic institutions and other organizations currently have programs to develop COVID-19 vaccine candidates.

XIII. Legal Proceedings

We are and may be involved in various legal proceedings, including patent litigation, product liability and other product-related litigation, as well as other legal proceedings that arise from time to time in the ordinary course of business, including, but not limited to, personal injury, consumer, off-label promotion, securities, antitrust, employment law, tax, environmental, and/or other claims or investigations.

Our contingencies include, but are not limited to, intellectual property disputes and product liability and other product-related litigation. From time to time, in the normal course and conduct of our business, we may be involved in discussions with third parties about considering, for example, the use and/or remuneration for use of such third party's intellectual property. As of December 31, 2023, none of such intellectual property-related considerations that we have been notified of, and for which potential claims could be brought against us or our subsidiaries in the future, fulfill the criteria for recording a provision. We are subject to an increasing number of product liability claims. Such claims often involve highly complex issues related to medical causation, correctness and completeness of product information (Summary of Product Characteristics/package leaflet) as well as label warnings and reliance thereon, scientific evidence and findings, actual and provable injury, and other matters. These complexities vary from matter to matter. As of December 31, 2023, none of these claims fulfill the criteria for recording a provision. Substantially all of our contingencies are subject to significant uncertainties and, therefore, determining the likelihood of a loss and/or the measurement of any loss can be complex. Consequently, we are unable to estimate the range of reasonably possible loss. Our assessments, which result from a complex series of judgments about future events and uncertainties, are based on estimates and assumptions that have been deemed reasonable by management, but that may prove to be incomplete or inaccurate, and unanticipated events and circumstances may occur that might cause us to change those estimates and assumptions. We currently do not believe that any of these matters will have a material adverse effect on our financial position, and will continue to monitor the status of these and other claims that may arise. However, we could incur judgments, enter into settlements or revise our expectations regarding the outcome of matters, which could have a material adverse effect on our results of operations and/or our cash flows in the period in which the amounts are accrued or paid. We will continue to evaluate whether, if circumstances were to change in the future, the recording of a provision may be needed and whether potential indemnification entitlements exist against any such claim.

Certain pending matters to which we are a party are discussed below.

For a description of the risks relating to these and other legal proceedings we face and may in the future face and our assessments thereof, see "Risk Factors" elsewhere in this Annual Report.

Alnylam Proceedings

In March 2022, Alnylam Pharmaceuticals, Inc., or Alnylam, filed a lawsuit against Pfizer and Pharmacia & Upjohn Co. LLC in the U.S. District Court for the District of Delaware alleging that an existing patent owned by Alnylam, U.S. Patent No. 11,246,933, or the '933 Patent, is infringed by the cationic lipid used in *Comirnaty*, and seeking monetary relief, which is not specified in their filings. We filed a counterclaim to become party to the Alnylam proceeding, and in June 2022, Alnylam added to its claims allegations that we induced infringement of the '933 Patent. Additionally, in July 2022, Alnylam filed a lawsuit against us, our wholly owned subsidiary, BioNTech Manufacturing GmbH, Pfizer and Pharmacia & Upjohn Co. LLC in the U.S. District Court for the District of Delaware alleging that we also induced infringement of a newly issued patent, U.S. Patent No. 11,382,979, or the '979 Patent, which is a continuation of the '933 Patent. The two lawsuits were consolidated on July 28, 2022. In May 2023, Alnylam filed a third lawsuit against Pfizer Inc. and Pharmacia & Upjohn Co. LLC in the U.S. District Court for the District of Delaware alleging infringement of U.S. Patent Nos. 11,633,479; 11,633,480; 11,612,657; and 11,590,229, all of which are continuations of the '933 Patent. We filed a counterclaim to become party to the new proceeding, and in July 2023, Alnylam added to its claims allegations that we induced infringement of the four new patents. All of the proceedings have been consolidated and are currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the proceedings mentioned above. However, our analysis of Alnylam's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

CureVac Proceedings

Germany

Infringement Proceedings – EP’122, DE’961, DE’974, DE’575, and EP’668

In July 2022, CureVac AG, or CureVac, filed a lawsuit against us and our wholly owned subsidiaries, BioNTech Manufacturing GmbH and BioNTech Manufacturing Marburg GmbH, in the Düsseldorf Regional Court, alleging *Comirnaty*’s infringement of one European patent, EP1857122B1, or the EP’122 Patent, and three Utility Models DE202015009961U1, DE202015009974U1, and DE202021003575U1. In August 2022, CureVac added European Patent EP3708668B1, or the EP’668 Patent, to its German lawsuit.

On August 15, 2023, the Düsseldorf Regional Court held a hearing on infringement with respect to all five IP rights. At the hearing, the Court suspended its infringement ruling with respect to EP’122 until December 28, 2023. On September 28, 2023, the Court issued orders suspending its infringement rulings with respect to the remaining four IP rights (DE’961, DE’974, DE’575, and EP’668) pending validity decisions in the DE’961, DE’974, and DE’575 cancellation proceedings before the German Patent and Trademark Office and in the EP’668 opposition proceedings before the Opposition Division of the European Patent Office. In the September 28th orders, the Court explained that it was suspending its infringement rulings until validity decisions are reached, while contemporaneously noting concerns regarding the validity of DE’961, DE’974, DE’575, and EP’668. On December 28, 2023, the Düsseldorf Regional Court stayed the infringement proceedings as to EP’122 until a final appellate decision is rendered as to the validity of EP 122 by the Federal Court of Justice.

Infringement Proceedings – EP’755, DE’123, and DE’130

In July 2023, CureVac SE filed a second lawsuit against us and our wholly owned subsidiaries, BioNTech Manufacturing GmbH and BioNTech Manufacturing Marburg GmbH, in the Düsseldorf Regional Court, alleging *Comirnaty*’s infringement of one European patent, EP4023755B1, or the EP’755 Patent, and two Utility Models DE202021004123U1, and DE202021004130U1.

Nullity Proceedings – EP’122

In September 2022, we filed a nullity action in the Federal Patent Court of Germany seeking a declaration that the EP’122 Patent is invalid. In April 2023, the Federal Patent Court of Germany issued a preliminary opinion in the EP’122 nullity action in support of the validity of the EP’122 Patent. The preliminary opinion did not address any infringement of the EP’122 Patent. The preliminary opinion is a preliminary assessment by the court of the merits of a claim, and is non-binding. On December 19, 2023, the Federal Patent Court held an oral hearing, after which it nullified EP’122.

Cancellation Proceedings – DE’961, DE’974, and DE’575

In November 2022, we filed cancellation actions seeking the cancellation of the three German Utility Models in the German Patent and Trademark Office. On December 27, 2023, the German Patent Office issued a preliminary opinion that DE’974 is likely to be cancelled based on invalidity pursuant to para. 1 (2) no. 5 Utility Model Act.

United States

In July 2022, we and Pfizer filed a complaint for a declaratory judgment in the U.S. District Court for the District of Massachusetts, seeking a judgment of non-infringement by *Comirnaty* of U.S. Patent Nos. 11,135,312, 11,149,278 and 11,241,493. In May 2023, the action in the U.S. District Court for the District of Massachusetts was transferred to the U.S. District Court for the Eastern District of Virginia, where CureVac filed counterclaims asserting infringement of six additional U.S. patents, U.S. Patent Nos. 10,760,070; 11,286,492; 11,345,920; 11,471,525; 11,576,966; and 11,596,686. In July 2023, CureVac filed amended counterclaims to assert an additional U.S. patent, U.S. Patent No. 11,667,910.

United Kingdom

In September 2022, we and Pfizer filed a declaration of non-infringement and revocation action against the EP’122 Patent and the EP’668 Patent in the Business and Property Courts of England and Wales. In October 2022, CureVac responded by filing a counterclaim alleging infringement of the EP’122 and EP’668 patents in the Business And Property Courts of England and Wales. On December 18, 2023, we amended our pleadings to further allege non-infringement and invalidity against EP’755.

All of the above proceedings are currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and utility models and intend to vigorously defend ourselves in the proceedings mentioned above. However, our analysis of CureVac's claims is ongoing and complex, and we believe the ultimate outcomes remain substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

Moderna Proceedings

Germany

Infringement Proceedings – EP'949 and EP'565

In August 2022, Moderna filed a lawsuit against us and Pfizer and our wholly owned subsidiaries, BioNTech Manufacturing GmbH, BioNTech Europe GmbH and BioNTech Manufacturing Marburg GmbH, Pfizer Manufacturing Belgium NV, Pfizer Ireland Pharmaceuticals and Pfizer Inc. in the Düsseldorf Regional Court alleging Comirnaty's infringement of two European Patents, 3590949B1, or the EP'949 Patent, and 3718565B1, or the EP'565 Patent. On November 7, 2023, the European Patent Office ("EPO") Opposition Division revoked EP'565 after a one-day oral hearing. The Opposition Division issued a preliminary opinion on December 8, 2023 noting that it believes EP'949 is likely invalid. As a result of these EPO proceedings, the Düsseldorf Regional Court postponed its hearing on infringement, originally scheduled for December 12, 2023, to January 21, 2025.

United Kingdom

In August 2022, Moderna filed a lawsuit asserting *Comirnaty's* infringement of the EP'949 Patent and EP'565 Patent against us and our wholly owned subsidiaries, BioNTech Manufacturing GmbH, BioNTech Europe GmbH and BioNTech Manufacturing Marburg GmbH, Pfizer Limited, Pfizer Manufacturing Belgium NV and Pfizer Inc. in the Business and Property Courts of England and Wales. In September 2022, we and Pfizer filed a revocation action in the Business and Property Courts of England and Wales requesting revocation of the EP'949 Patent and EP'565 Patent.

United States

U.S. District Court Litigation

In August 2022, Moderna filed a lawsuit in the United States District Court for the District of Massachusetts against us and our wholly owned subsidiaries BioNTech Manufacturing GmbH and BioNTech US Inc. and Pfizer Inc. alleging *Comirnaty's* infringement of U.S. Patent Nos. 10,898,574, 10,702,600 and 10,933,127 and seeking monetary relief.

Inter Partes Review

In August 2023, Pfizer and we filed petitions seeking inter partes review of U.S. Patent Nos. 10,702,600 and 10,933,127 before the United States Patent Trial and Appeal Board.

Netherlands

In September 2022, Moderna filed a lawsuit against us and our wholly owned subsidiary BioNTech Manufacturing GmbH and Pfizer B.V., Pfizer Export B.V., C.P. Pharmaceuticals International C.V. and Pfizer Inc. in the District Court of The Hague alleging *Comirnaty's* infringement of the EP '949 Patent and the EP '565 Patent. The District Court of the Hague held a hearing on October 6, 2023 on infringement and validity with respect to the EP '949 Patent. On December 6, 2023, the Court found EP'949 to be invalid. The EP'565 case has been stayed pending Moderna's appeal of the Opposition Division's revocation of EP'565.

Ireland

In May 2023, Moderna filed a lawsuit against us and our wholly owned subsidiary BioNTech Manufacturing GmbH, Pfizer Inc., Pfizer Healthcare Ireland, Pfizer Ireland Pharmaceuticals, and C.P. Pharmaceuticals International C.V. alleging *Comirnaty's* infringement of the EP'949 Patent and EP'565 Patent in the High Court of Ireland.

Belgium

In May 2023, Moderna filed a lawsuit against us, our wholly owned subsidiary BioNTech Manufacturing GmbH, Pfizer Inc. and Pfizer Manufacturing Belgium alleging *Comirnaty*'s infringement of the EP'949 Patent and the EP'565 Patent in the Brussels Dutch-speaking Enterprise Court.

All of the above proceedings are currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the proceedings mentioned above. However, our analysis of Moderna's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

Arbutus and Genevant Proceedings

In April 2023, Arbutus Biopharma Corp., or Arbutus, and Genevant Sciences GmbH, or Genevant, filed a lawsuit against Pfizer and us in the U.S. District Court for the District of New Jersey alleging that Pfizer and we have infringed the following patents owned by Arbutus: U.S. Patent Nos. 9,504,651; 8,492,359; 11,141,378; 11,298,320; and 11,318,098, through the use of Genevant's lipid nanoparticle technology and methods for producing such lipids in *Comirnaty*, and seeking monetary relief. This proceeding is currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the lawsuit mentioned above. However, our analysis of Arbutus and Genevant's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

Promosome Proceedings

In June 2023, Promosome LLC filed a lawsuit against Pfizer, us, and BioNTech Manufacturing GmbH in the U.S. District Court for the Southern District of California alleging that Pfizer and our *Comirnaty* vaccine has infringed U.S. Patent No. 8,853,179, and seeking monetary relief. On October 4, 2023, the parties filed a joint stipulation of dismissal, dismissing the lawsuit with prejudice. As part of this stipulation of dismissal, Promosome agreed to a covenant not to assert U.S. Patent No. 8,853,179 against Pfizer and us or any of their products, including *Comirnaty*. This matter is considered closed.

C. Organizational Structure

See Item 18.

D. Property, Plant and Equipment

The following is a summary of our principal owned and leased real estate. We also lease other properties in the ordinary course of business as part of our global operations.

Germany:

Our headquarters are located in Mainz, where we principally occupy:

- Approximately 9,416 square meters of laboratory, GMP manufacturing, storage and office space at An der Goldgrube 12, 55131. We acquired ownership of the building in December 2022.
- Approximately 8,446 square meters of office and laboratory container space at Freiligrathstraße 6, 55131. The lease of the office container space expires on June 30, 2027. We own the laboratory container space.
- Approximately 1,049 square meters of office and GMP manufacturing space under a lease for part of the building located at Kupferbergterstraße 15, 55161 under a lease that expires on March 31, 2027.

- Approximately 4,882 square meters of laboratory and office space located at Adam-Opel-Straße 10, 55129, which is owned by us, as well as 9,278 square meters of undeveloped land intended for construction of a laboratory and office building of up to 12,000 square meters in size. Currently the land is occupied by approximately 2,125 square meters of office container space.
- We also own a plot of land of approximately 8,753 square meters at Hechtsheimer Straße 2b, 55131, where construction for a GMP manufacturing facility of approximately 18,000 square meters commenced in 2021.
- Approximately 42,164 square meters of office space under a lease for two of three building parts at Große Bleiche 54-56, 55131, under a lease that expires on December 31, 2029.

In Idar-Oberstein:

- The IMFS facility (consisting of buildings A to E and J) has a total area of approximately 13,470 square meters. This includes approximately 2,660 square meters of storage space, approximately 1,270 square meters of development and QC laboratory space, approximately 1,650 square meters of clean rooms, and approximately 2,540 square meters are office space. This facility, including the GMP-certified manufacturing suites, is owned by BioNTech.
 - We occupy approximately 575 square meters of this space, which is used primarily for storage, under a lease that has an initial expiry date of October 1, 2021, but which we have extended until September 30, 2026. The warehouse is located in Tiefenstein.
 - We have been renting the warehouse for GMP products since April 2022. The warehouse has an area of 1,120 square meters. The term is 5 years with the option to extend.
 - Rental of a plot of land with 2,000 square meters. A container facility was built on it. The office container facility has a size of approximately 2,125 square meters. Both contracts currently run until June 2025.

In Marburg:

Behringwerke

- Our main manufacturing facility consists 10,240 square meters, including 4,589 square meters of GMP space, 2,422 square meters of technical and storage facilities, 540 square meters of laboratory space and 2,690 square meters of offices. The lease will expire December 31, 2034.
- Our main office building consists of 4,913 square meters of office space. The lease will expire until October 31, 2027.
- We also occupy 920 square meters of office space under a lease which will expire on May 31, 2026.
- We have leased additional 779 square meters of technical and storage facilities under a lease which will expire on December 31, 2024.

Görzhausen

- As part of our *BioNTainer* program (BioNTech Innovation Center/BIC), we occupy approximately 2,040 square meters. Approximately 804 square meters are used as office space and 1,236 square meters are used as GMP and technical storage facilities under a lease which will expire December 31, 2031.
- Our own Plasmid Production/Miami (Microbial Manufacturing) is located in M537 and M536. In M537 we occupy 3,088 square meters, including 1,021 square meters of usable GMP and laboratory space, 1,065 square meters of usable technical and storage facilities and 448 square meters of usable office space. In M536 we occupy 164 square meters. The lease will expire December 31, 2031.

In Berlin:

- At our JPT facility, we occupy approximately 2,390 square meters of office, laboratory and general technical production space:
 - About 2,050 square meters are occupied under a lease contract, which will expire simultaneously to our moving into our new building.

- For the remaining approximately 350 square meters of office space, we have a lease contract with a firm term until 2026.
- A new laboratory and office building, wholly owned by JPT, is under construction, with an expected completion date in mid-2025.
- We have been renting an office of approximately 1,700 square meters since April 2023. The contract runs until December 31, 2028. Extension options are possible.

In Munich, we have leased approximately 3,700 square meters in the Werksviertel. The lease is for 60 months with options to extend.

In Martinsried, we occupy approximately 1,862 square meters under a lease which will expire on December 31, 2026.

In Neuried:

- We occupy approximately 1,732 square meters of laboratory and office space under a lease which will expire on November 30, 2031.
- We leased additional space in July 2022 of approximately 1,470 square meters of laboratory, office and storage space under a lease which will expire on August 30, 2029.

In Fussgoenheim, we lease approximately 3,448 square meters of freezer farm space.

In Mutterstadt, we occupy approximately 5,744 square meters of freezer farm space under a rental agreement. We also lease a further 2,160 square meters of handling space. The term ends on December 31, 2027, with a one-year extension option.

In Halle, we have rented an area of approximately 1,100 square meters, including approximately 100 square meters of laboratory space. The lease runs until spring 2025, with an option to extend.

We intend to expand our capacity as follows:

- In January 2022, we commenced construction of a four-story building at An der Goldgrube 10 in Mainz, which we will own. We have planned laboratory space for research and development, offices, storage facilities, a conference center and cafeteria. As a result, we will take up an additional 2,400 square meters of main laboratory space and 4,000 square meters of main office space.

Global locations:

In Cambridge, Massachusetts, United States, we principally occupy:

- Approximately 2,490 square meters of laboratory and office space under a lease for part of a building located at 40 Erie Street that has an initial term that expires on September 30, 2024.
- Approximately 4,410 square meters of laboratory and office space under a lease for part of a building located at 75 Sidney Street that has an initial term that expires on January 31, 2032.

In Gaithersburg, Maryland, United States, we principally occupy:

- Approximately 5,476 square meters under a lease which will expire on July 31, 2033.
- Approximately 823 square meters of laboratory and office space under a lease which will expire on July 31, 2033.

In Cambridge, England, we principally occupy:

- Approximately 120 square meters of laboratory and office space under a lease at the MRC-Laboratory of Molecular Biology with an initial term until December 31, 2024.

- Approximately 7,400 square meters of shell and core laboratory and office space under a lease with an initial term until October 13, 2033, including a tenant only break option at year 7 of the term. The building is expected to be in operation during 2025.

In Vienna, Austria, we signed a lease in September 2022 for approximately 1,300 square meters of office and laboratory space for part of the building located at Helmut-Qualtinger-Gasse 2, 1030. The lease commenced on April 1, 2023, with a lease term of eight years and an option to extend.

In Kigali, Rwanda, we have leased a plot of land of approximately 35,100 square meters to develop an mRNA vaccine factory for the manufacturing of bulk drug substance and bulk drug product.

In Singapore, we will own a production site. The purchase will close in April 2024. The entire area covers approximately 63,300 square meters. The building is currently being upgraded. After completion, there will be office space of approximately 6,195 square meters, a production and technical building of approximately 20,000 square meters, and a warehouse of approximately 3,400 square meters.

Item 4A. Unresolved Staff Comments

None.

Item 5. Operating and Financial Review and Prospects

The following "Operating and Financial Review and Prospects" discussion should be read together with the information in our financial statements and related notes included elsewhere in this Annual Report. The following discussion is based on our financial information prepared in accordance with the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, which may differ in material respects from generally accepted accounting principles in other jurisdictions, including U.S. GAAP. The following discussion includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described in "Risk Factors" and elsewhere in this Annual Report. Please also see "Cautionary Statement Regarding Forward-Looking Statements."

A. Operating Results

Financial Operations Overview

The following table shows our consolidated statements of profit or loss for each period presented:

<i>(in millions €)</i>	Years ended December 31,		
	2023	2022	2021
Revenues			
Commercial revenues	3,815.5	17,194.6	18,874.0
Research & development revenues	3.5	116.0	102.7
Total revenues	3,819.0	17,310.6	18,976.7
Cost of sales	(599.8)	(2,995.0)	(2,911.5)
Research and development expenses	(1,783.1)	(1,537.0)	(949.2)
Sales and marketing expenses	(62.7)	(59.5)	(50.4)
General and administrative expenses	(495.0)	(481.7)	(276.8)
Other operating expenses	(293.0)	(410.0)	(103.4)
Other operating income	105.0	815.3	598.4
Operating income	690.4	12,642.7	15,283.8
Finance income	519.6	330.3	67.7
Finance expenses	(23.9)	(18.9)	(305.1)
Profit before tax	1,186.1	12,954.1	15,046.4
Income taxes	(255.8)	(3,519.7)	(4,753.9)
Profit for the period	930.3	9,434.4	10,292.5
Earnings per share			
Basic earnings for the period per share	3.87	38.78	42.18
Diluted earnings for the period per share	3.83	37.77	39.63

Comparison of the year ended December 31, 2023 and the year ended December 31, 2022

Revenues

The following is a summary of revenues recognized for the periods indicated:

<i>(in millions €)</i>	Years ended December 31,		Change	
	2023	2022	€	%
Revenues				
Commercial revenues	3,815.5	17,194.6	(13,379.1)	(78)
COVID-19 vaccine revenues	3,776.2	17,145.2	(13,369.0)	(78)
<i>Sales to collaboration partners</i>	275.3	1,224.3	(949.0)	(78)
<i>Direct product sales to customers</i>	473.6	3,184.7	(2,711.1)	(85)
<i>Share of collaboration partners' gross profit</i>	3,027.3	12,736.2	(9,708.9)	(76)
Other sales	39.3	49.4	(10.1)	(20)
Research & development revenues from collaborations	3.5	116.0	(112.5)	(97)
Total revenues	3,819.0	17,310.6	(13,491.6)	(78)

Commercial Revenues

From the year ended December 31, 2022 compared to the year ended December 31, 2023 commercial revenues decreased by €13,379.1 million from €17,194.6 million to €3,815.5 million, in line with a lower COVID-19 vaccine market demand. We are the marketing authorization holder in the United States, the European Union, the United Kingdom, Canada and other countries, and holder of EUAs or equivalents in the United States (jointly with Pfizer) and other countries. Pfizer has marketing and distribution rights worldwide with the exception of China, Germany and Türkiye. Fosun Pharma, has marketing and distribution rights in China, Hong Kong special administrative region, or SAR, Macau SAR and the region of Taiwan. The allocation of marketing and distribution rights defines territories in which the collaboration partners act as a principal.

Sales to collaboration partners represent sales of products manufactured by us to collaboration partners. Whenever responsibilities in the manufacturing and supply process of the COVID-19 vaccine shift and the COVID-19 vaccine is transferred, the vaccine is sold from one partner to the other. Under the collaboration with Pfizer, from time to time, those sales are significantly influenced by amounts due to write-downs of inventories as well as costs related to production capacities derived from contracts with CMOs that became redundant. Those costs represent accrued manufacturing variances and are charged to our partner once finally materialized. These manufacturing variances are reflected as transfer price adjustments once identified. The regular reassessment of these manufacturing variances may result in adjustments to the respective prior-period revenues. Sales to collaboration partners during the years ended December 31, 2023, and 2022, amounted to €275.3 million and €1,224.3 million, respectively. During the years ended December 31, 2023, and 2022 those sales included €74.5 million and €850.0 million, respectively, related to the aforementioned manufacturing variances.

Direct product sales are recognized from supplying COVID-19 vaccine in our territories Germany and Türkiye. During the years ended December 31, 2023, and 2022, we recognized €473.6 million and €3,184.7 million of revenues, respectively. The share of gross profit that we owe our collaboration partner Pfizer based on our sales is recognized as cost of sales.

Based on COVID-19 vaccine sales in the collaboration partners' territories, we are eligible to receive a share of their gross profit, which represents a seasonally affected net figure and is recognized as collaboration revenue during the commercial phase, together with sales milestones. Manufacturing cost variances either reflected as transfer price adjustments as described above or resulting from costs highly probable to be incurred by the partner, were taken into account when determining the gross profit. During the year ended December 31, 2023, €3,027.3 million gross profit share has been recognized as revenue. During the year ended December 31, 2022, €12,736.2 million gross profit share has been recognized as revenues.

Research & Development Revenues from Collaborations

From the year ended December 31, 2022 compared to the year ended December 31, 2023, research and development revenues from collaborations decreased by €112.5 million or 97% from €116.0 million to €3.5 million. This was mainly effected by one-time effects from our collaborations with Pfizer and Sanofi S.A, or Sanofi.

Cost of Sales

From the year ended December 31, 2022 to the year ended December 31, 2023, cost of sales decreased by €2,395.2 million or 80% from €2,995.0 million to €599.8 million, mainly due to recognizing lower cost of sales from our decreased COVID-19 vaccine sales, which included the share of gross profit that we owe our collaboration partner Pfizer based on our sales. In addition, cost of sales was impacted by expenses arising from inventory write-offs and expenses for production capacities derived from contracts with CMOs that became redundant. The effects were driven by reducing production capacities as well as further fostering the global production network with our collaboration partners during the year ended December 31, 2023.

Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated:

<i>(in millions €)</i>	Years ended December 31,		Change	
	2023	2022	€	%
Research and development expenses⁽¹⁾				
COVID-19	313.0	550.0	(237.0)	(43.1)
Non-COVID-19	1,470.1	987.0	483.1	48.9
Total research and development expenses	1,783.1	1,537.0	246.1	16.0

⁽¹⁾ Break-down as per internal cost allocation logic.

From the year ended December 31, 2022 to the year ended December 31, 2023, our research and development expenses increased by €246.1 million or 16% from €1,537.0 million to €1,783.1 million, mainly influenced by progressing clinical studies for pipeline candidates as well as by our newly acquired product candidates and the development of variant adapted COVID-19 vaccines. The increase was further driven by an increase in wages, benefits and social security expenses resulting from a significant increase in headcount.

Sales and Marketing Expenses

From the year ended December 31, 2022 to the year ended December 31, 2023, our sales and marketing expenses increased by €3.2 million or 5% from €59.5 million to €62.7 million, mainly due to increased expenses for setup and enhancement of commercial IT platforms and an increase in wages, benefits and social security expenses resulting from an increase in headcount.

General and Administrative Expenses

From the year ended December 31, 2022 to the year ended December 31, 2023, our general and administrative expenses increased by €13.3 million or 3% from €481.7 million to €495.0 million, mainly influenced by increased expenses for IT services as well as by wages, benefits and social security expenses resulting from an increase in headcount.

Other Operating Income / Expenses

From the year ended December 31, 2022 to the year ended December 31, 2023, our other result decreased by €593.3 million or 146% from positive €405.3 million to a negative result of €188.0 million. The other operating result reflected the change in foreign exchange rates and included net negative foreign exchange differences during year ended December 31, 2023 compared to net positive foreign exchange differences during the previous year period that related to our U.S. dollar denominated trade receivables which were mainly incurred under our COVID-19 vaccine collaboration with Pfizer, U.S. dollar denominated trade payables as well as U.S. dollar denominated other financial liabilities which mainly relate to obligations incurred from our license agreements. The amounts were offset by recording the change in fair value of foreign

exchange forward contracts that were entered to manage some of our transaction exposures but were not designated as hedging instruments under IFRS.

Finance Income / Expenses

From the year ended December 31, 2022 to the year ended December 31, 2023, our total financial result increased by €184.3 million from a positive financial result of €311.4 million to a positive financial result of €495.7 million, which was driven by interest income earned on bank deposits and financial securities as well as fair value adjustments in relation to our money market funds. During the year ended December 31, 2022, the fair value adjustments derived from remeasuring the derivative embedded in our convertible note significantly affected our finance result.

Income Taxes

The following table summarizes our income taxes for the periods indicated:

<i>(in millions €)</i>	Years ended December 31,		Change	
	2023	2022	€	%
Current income taxes	243.1	3,629.6	(3,386.5)	(93)
Deferred taxes	12.7	(109.9)	122.6	(112)
Income taxes	255.8	3,519.7	(3,263.9)	(93)

Our current income taxes represent mainly corporate and trade taxes derived by our German tax group. The decrease in profit during the year ended December 31, 2023 led to lower taxable income for the year ended December 31, 2023 for the German tax group. Corporate and trade tax prepayments have been made exceeding the tax charge. Refunds will become due once tax declarations have been filed and assessed.

As of December 31, 2023, our accumulated tax losses comprised tax losses of German entities that were incurred prior to the establishment of a tax group with BioNTech SE or by entities that are not within the tax group (as of December 31, 2023: BioNTech Real Estate Verwaltungs GmbH; as of December 31, 2022: BioNTech BioNTainer Holding GmbH, BioNTech Idar-Oberstein Services GmbH, NT Security and Services GmbH, BioNTech Real Estate Verwaltungs GmbH and the Real Estate partnerships) or U.S. tax group.

The amount of deductible temporary differences, unused tax losses, and unused tax credits for which no deferred tax asset is recognized in the statement of financial position as of December 31, 2023 is €531.5 million. Thus as of December 31, 2023, we have not recognized deferred tax assets for unused tax losses and temporary differences in an amount of €138.0 million (December 31, 2022: €136.7 million) as the criteria of the recognition guidance for IAS 12, which requires that no reliance should be placed on future events that cannot be controlled and are uncertain, are not met. Unrecognized deferred tax assets are re-assessed at each reporting date and are recognized to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

A reorganization of the intellectual property rights within the group has become effective June 30, 2023 and July 1, 2023 which led to deferred tax effects in Germany, the US and Austria. As a result BioNTech SE recognized deferred tax assets and deferred tax income at the time of the transaction. In addition this transaction led to a revaluation of previously unrecognized U.S. federal and state deferred tax assets, including unused tax losses and unused tax credits. As of December 31, 2022, there were unrecognized U.S. federal and state deferred tax assets of €128.9 million. As of December 31, 2023, it is considered highly probable that taxable profits for the U.S. tax group will be available against which the deferred tax assets can be utilized in the near future, fulfilling the requirements set out by IAS 12. Therefore we no longer continue to maintain the full non-recognition of deferred tax assets of our U.S. tax group as there will be future taxable profits available against which the unused tax losses and temporary differences can be utilized. As of December 31, 2023, we maintain the non-recognition of deferred tax assets for unused U.S. federal and state tax losses and tax credits at an amount of €31.9 million and €2.8 million, respectively, as there is not sufficient probability in terms of IAS 12 that future taxable income will be available against which these unused tax losses can be utilized. The material unrecognized U.S. federal and state tax losses and tax credits will begin to expire in 2036.

The realization of deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are subject to uncertainties. We may become subject to income tax audits and adjustments by local tax

authorities. The assessments of the recoverability of deferred tax assets and the nature of uncertain tax positions are subject to significant judgment by management and subject to change.

The groups does not recognize deferred tax liabilities for taxable temporary differences associated with investments in subsidiaries, in cases where the group is able to control the timing of the reversal of the temporary difference and it is probable that the temporary differences will not reverse in the foreseeable future. The aggregate amount of temporary differences associated with investments in subsidiaries, for which deferred tax liabilities have not been recognized is €2.8 million.

Information about Our Operating Segments

Decisions with respect to business operations and resource allocations are made by our Management Board, as the chief operating decision maker (CODM) based on BioNTech as a whole. Accordingly, we operate and make decisions as a single operating segment, which is also our reporting segment.

Related Party Transactions

Related party transactions that occurred during the years ended December 31, 2023, and 2022 are explained in Item 7. of this Annual Report as well as in Note 21 of our consolidated financial statements included elsewhere in this Annual Report.

Key Performance Indicators

Financial key performance indicators

The following financial performance indicators are the focus of managing our operational business development. We use the key figures on the basis of current exchange rates (not currency-adjusted) and take into account the effects of potential M&A activities or collaborations to the extent that they are published.

Revenues

Total revenues mainly comprises expected commercial revenue, particularly in connection with our COVID-19 business as well as other revenue sources. Revenues are heavily influenced by the volumes available under the collaboration and the agreed upon purchase quantities. As our revenues represent our share of the collaboration partners' gross profit, they are also influenced by the incurring costs. For further information on the composition of commercial COVID-19 vaccine sales and the components contained therein, see the comments on sales under Item 5. Operating Results. Our sales serve as a performance indicator of our commercial earning power.

Research and development expenses

Research and development expenses are an indicator of our future earnings potential, as this is highly dependent on the development of the clinical pipeline and the responsible use of the financial resources generated. This figure mainly includes expenses for the development of our clinical product candidates, early exploratory research and research and development overhead costs.

Sales, general and administrative expenses

These costs include sales and marketing costs as well as general and administrative costs. We use this measure to manage the costs associated with the expansion of the sales and marketing organization to ensure the necessary infrastructure and digital capacity for future market-ready products, as well as to manage the internal administrative and coordination functions associated with the expansion of research and development, such as finance, human resources, or business development, with regard to the associated cost development.

In addition, we also use the following financial performance indicators:

Investments in property, plant and equipment and intangible assets

Capital expenditures for property, plant and equipment and intangible assets include expenditures for the acquisition of property, plant and equipment as well as expenditures for the acquisition of intangible assets and rights of use, unless they are made as part of business combinations. These mainly include expenditures for the expansion and improvement of

our research and development and manufacturing facilities and investments in a state-of-the-art IT infrastructure to support the company in all digitization projects.

Non-financial key performance indicators

R&D Pipeline progress

Progress in research achievements, such as the development and commercialization of the COVID-19 vaccine, is a key performance indicator. We are working to clinically demonstrate the benefit of additional treatment approaches, further develop additional product candidates in the form of pivotal studies, and continuously expand collaborations and manufacturing capabilities to offer innovative treatments to patients around the world.

B. Liquidity and Capital Resources

Given our strong financial, scientific and operational accomplishments, we believe we have the resources to diligently allocate our current capital to drive a multi-platform strategy and deliver a fully integrated global biotechnology company. We focus our research and development (R&D) on rapidly advancing our diversified clinical oncology pipeline with synergistic potential, developing next generation COVID-19 vaccines to maintain leadership and pandemic preparedness as well as broaden the label of and access to the existing vaccine. We also plan to invest heavily to build out our global development organization, bringing in talent with clinical and regulatory expertise needed to accelerate our pipeline development. We are also diversifying our therapeutic area footprint which will enable us to fully leverage the potential of all technology platforms across autoimmune diseases, inflammatory diseases, cardiovascular disease, neurodegenerative diseases, and regenerative medicines. In addition, we plan to enhance capabilities through complementary acquisitions, technologies, infrastructure and manufacturing. To support our future trajectory, growing the organization and expanding our team is of utmost importance. We are on the way to develop our global footprint in key regions including Europe, the United States, Asia and Africa. Additionally, investing in manufacturing capabilities for key technologies and deploying our pandemic response capabilities remain priorities for us. As a science and innovation driven company, we will continue to focus investments on R&D and scaling the business for commercial readiness in oncology in multiple countries by the end of 2025.

As of December 31, 2023, we had cash and cash equivalents of €11,663.7 million and security investments of €5,989.7 million accumulating to €17,653.4 million cash and security investments. Our trade receivables of €2,155.7 million outstanding as of December 31, 2023 were mainly due to the contractual settlement of the gross profit share under our COVID-19 collaboration with Pfizer as described in Note 6 to our consolidated financial statements included elsewhere in this Annual Report. As of December 31, 2023, our trade receivables included, in addition to the profit share for the fourth quarter of 2023, trade receivables which related to the gross profit share for the third quarter of 2023.

Cash and cash equivalents and financial securities are invested in accordance with our asset management and investment policy, primarily with a focus on liquidity and capital preservation, and consist primarily of cash in bank accounts and on hand as well as long- and short-term financial investments.

In January 2022, we announced a new research, development and commercialization collaboration with Pfizer to develop a potential first mRNA-based vaccine for the prevention of shingles (herpes zoster virus, or HZV). Under the terms of the agreement, Pfizer will pay \$225.0 million in upfront payments, including a cash payment and an equity investment as we will pay Pfizer \$25.0 million for the company's proprietary antigen technology. In addition, we are eligible to receive future regulatory and sales milestone payments of up to \$200.0 million as well as a share of gross profits arising from future product sales. The issuance of 245,284 ordinary shares with the nominal amount of €0.5 million was registered with the commercial register (Handelsregister) on March 24, 2022.

In March 2022, our Management Board and Supervisory Board authorized the 2022 share repurchase program of ADSs, pursuant to which we were permitted to repurchase ADSs, each representing one ordinary share, with a value of up to \$1.5 billion a two-year period, commencing on May 2, 2022. The first tranche of our 2022 share repurchase program of ADSs, with a value of up to \$1.0 billion, concluded on October 10, 2022. The second tranche with a value of up to \$0.5 billion commenced on December 7, 2022 and concluded on March 17, 2023.

In March 2023, our Management Board and Supervisory Board authorized the 2023 share repurchase program, under which we were permitted to purchase ADSs, each representing one ordinary share, with a value of up to \$0.5 billion, which started June 2, 2023 and concluded on September 18, 2023.

In total 9,166,684 ADSs were repurchased under the 2022 program at an average price of \$142.05 (€138.37), for total consideration of \$1,302.0 million (€1,268.4 million). For the 2023 program, in total 4,646,965 ADSs were repurchased at an average price of \$107.58 (€98.24), for total consideration of \$500.0 million (€456.5 million).

In November 2020, we entered into a sales agreement, or the Sales Agreement, with Jefferies LLC and SVB Leerink LLC (nowknown as SVB Securities LLC), as sales agents, to establish an at-the-market offering program, pursuant to which we may sell, from time to time, ADSs representing ordinary shares for aggregate gross proceeds of up to \$500.0 million. During the year ended December 31, 2022, we sold 995,890 ADSs, each representing one of our ordinary shares and previously held in treasury, under the Sales Agreement. During the year ended December 31, 2021, the aggregate gross proceeds were \$200.0 million (€163.6 million). We did not sell any ADS during year ended December 31, 2023. The plan expired in November 2023.

Cash Flow

The following table summarizes the primary sources and uses of cash for each period presented:

<i>(in millions €)</i>	Years ended December 31,		
	2023	2022	2021
Net cash flows from / (used in):			
Operating activities	€5,371.4	€13,577.4	€889.7
Investing activities	(6,954.5)	(35.3)	(566.1)
Financing activities	(778.6)	(1,419.3)	94.2
Total cash inflow (outflow)	€(2,361.7)	€12,122.8	€417.8

Operating Activities

We derive cash flows from operations primarily from the sale of products and services rendered. Our cash flows from operating activities are significantly influenced by cash we generated as settlement payments of our gross profit as well as our use of cash for operating expenses and working capital to support the business. During the year ended December 31, 2023, our cash flows from operating activities include the settlement payments of our gross profit share from our collaboration partner Pfizer as scheduled by the contractual arrangement. As described in Note 6.2 to the consolidated financial statements included elsewhere in this Annual Report, the contractual settlement of the gross profit share has a temporal offset of more than one calendar quarter.

Net cash generated in operating activities for the year ended December 31, 2023 was €5,371.4 million, comprising a profit before tax of €1,186.1 million, negative non-cash adjustments of €393.2 million, and a net positive change in assets and liabilities of €5,574.8 million. Non-cash items primarily included net foreign exchange differences as well as share-based payment expenses without cash-effect. The net positive change in assets and liabilities was primarily due to a decrease in trade receivables related to our COVID-19 collaboration with Pfizer, as described in Note 6.2 to the consolidated financial statements included elsewhere in this Annual Report.

Net cash generated in operating activities for the year ended December 31, 2022 was €13,577.4 million, comprising a profit before tax of €12,954.1 million, positive non-cash adjustments of €370.9 million, and a net positive change in assets and liabilities of €4,518.5 million. Non-cash items primarily included net foreign exchange differences as well as share-based payment expenses without cash-effect. The net positive change in assets and liabilities was primarily due to a decrease in trade receivables related to our COVID-19 collaboration with Pfizer.

Net cash generated in operating activities for the year ended December 31, 2021 was €889.7 million, comprising a profit before tax of €15,046.4 million, positive non-cash adjustments of €56.0 million, and a net negative change in assets and liabilities of €10,730.4 million. Non-cash items primarily included movements in government grant, depreciation and amortization as well as share-based compensation expenses and non-cash effective finance expenses. The net negative change in assets and liabilities was primarily due to an increase in trade receivables and a decrease in payables and liabilities as well as inventories.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2023 was €6,954.5 million. The amount includes €5,912.1 million spend into security investments, €330.6 million caused by or driven from in-licensing arrangements as well as €336.9 million for collaborations or M&A transactions. Excluding those effects, the amount for capital expenditures supporting our operating activities amounts to €275.5 million whereof the majority was related to investments in building our laboratory and office facilities in Mainz, Germany.

Net cash used in investing activities for the year ended December 31, 2022 was €35.3 million, comprising the release of €375.2 million cash deposits and compensated by €329.2 million, which was attributable to the purchase of property, plant and equipment including the amounts spent with respect to the acquisition of the land and laboratory as well as the office facility of our headquarter in Mainz, Germany. Intangible assets investments amounted to €34.1 million, which was mainly attributable to certain patents and licenses. Therefore, the total capital expenditure spent on tangible and intangible assets during the year ended December 31, 2022 amounted to €363.3 million.

Net cash used in investing activities for the year ended December 31, 2021 was €566.1 million, comprising the investments of €375.2 million cash deposits, presented as financial assets as of December 31, 2021 due to their original term of six months, were shown as cash flow used in investing activities during the year ended December 31, 2021 but were returned to cash and cash equivalents during January and February 2022. In addition €127.5 million was attributable to the purchase of property, plant and equipment including the amounts spent with respect to our acquired facility in Gaithersburg, Maryland, United States as well as €20.8 million spent upon the acquisition of our new subsidiary in Vienna, Austria.

Financing Activities

Net cash used in financing activities for the year ended December 31, 2023 was €778.6 million, comprising the €738.5 million used for the share repurchase programs of ADS.

Net cash used in financing activities for the year ended December 31, 2022 was €1,419.3 million, comprising the €986.4 million used for the first tranche of our \$1.5 billion share repurchase program of ADS as well as the €484.3 million special cash dividend paid in June 2022. Whereas €110.5 million cash generated was attributable to the Pfizer equity investment as part of our HZV collaboration.

Net cash generated in financing activities for the year ended December 31, 2021 was €94.2 million, primarily generated from the sale of treasury shares under the at-the-market offering program net of transaction cost and offset by the amount spent when repaying our financing arrangement which was entered with the European Investment Bank, or the EIB.

Operation and Funding Requirements

As part of our capital allocation strategy, we expect to continue to incur significant and increasing operating expenses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we and our collaborators:

- continue or expand our research or development of our programs in preclinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional preclinical, clinical, or other trials for our product candidates, including under our collaboration agreements;
- continue to invest in our immunotherapy platforms to conduct research to identify novel technologies;
- change or increase our manufacturing capacity or capability;
- change or add additional suppliers;
- add additional infrastructure to our quality control, quality assurance, legal, compliance and other groups to support our operations as a public company and our product development and commercialization efforts, including new and expanded sites globally;
- attract and retain skilled personnel;
- seek marketing approvals and reimbursement for our product candidates;

- develop our sales, marketing, and distribution infrastructure for our COVID-19 vaccine and any other products for which we may obtain marketing approval or emergency use authorization;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- acquire other companies;
- make milestone or other payments under any in-license agreements;
- maintain, protect, defend, enforce and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

We are a party to license and research and development agreements with universities and other third parties, as well as patent assignment agreements, under which we have obtained rights to patents, patent applications and know-how. We enter into contracts in the normal course of business with CROs for clinical trials, clinical and commercial supply manufacturing, with vendors for preclinical research studies and for other services and products for operating purposes. We work together with CMOs, who manufacture our product candidates and products and enter into lease agreements to lease laboratory, GMP manufacturing, storage and office spaces. Purchase obligations under our agreements to the extent that they are quantifiable and not cancellable have been considered when defining our guidance for future cash commitments. Most of the committed cash outflow in 2024 is related to lease payments amounting to €34.1 million and commitments under purchase agreements and contractual obligations amounting to €401.9 million. Further, we have lease payment obligation with an amount of €210.3 million and commitments under purchase agreements and contractual obligations of €1,473.6 million for the years 2025 and beyond.

We are subject to all of the risks related to the development and commercialization of pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

Our future funding requirements, both near and long term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs, and results of preclinical or nonclinical studies and clinical trials for our product candidates;
- the amount and timing of revenues and associated costs from sales of our COVID-19 vaccine;
- the results of research and our other platform activities;
- the clinical development plans we establish for our product candidates;
- the terms of any agreements with our current or future collaborators, and the achievement of any milestone payments under such agreements to be paid to us or our collaborators;
- the number and characteristics of product candidates that we develop or may in-license;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable regulatory authorities;
- the cost of filing, prosecuting, obtaining, maintaining, protecting, defending and enforcing our patent claims and other intellectual property rights, including actions for patent and other intellectual property infringement, misappropriation and other violations brought by third parties against us regarding our product candidates or actions by us challenging the patent or intellectual property rights of others;
- the effect of competing technological and market developments, including other products that may compete with one or more of our product candidates;
- the cost and timing of completion and further expansion of clinical and commercial scale manufacturing activities sufficient to support all of our current and future programs;
- the cost of establishing sales, marketing, and distribution capabilities for any product candidates for which we may receive marketing approval and reimbursement in regions where we choose to commercialize our products on our own; and
- the terms of any ADS repurchases we make.

C. Research and Development, Patents and Licenses, etc.

Full details of our research and development activities and expenditures are given in Item 4 and under the description of the ‘Operating Results’ in this Item 5 within this Annual Report.

D. Trend Information

See the description of ‘Operating Results’ in this Item 5, ‘Business Overview’ in Item 4 and ‘Risk Factors’ in Item 3 within this Annual Report.

E. Critical Accounting Estimates

For a discussion of our Significant Accounting Judgments, Estimates and Assumption please refer to Note 3 to our consolidated financial statements included elsewhere in this Annual Report.

F. Comparison of the year ended December 31, 2022 and the year ended December 31, 2021

For a discussion of our operating results for the year ended December 31, 2021 and a comparison of the years ended December 31, 2022, and 2021 please refer to Item 5 of our Annual Report on Form 20-F for the year ended December 31, 2022.

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

Management Board (*Vorstand*)

On May 3, 2023, our Supervisory Board expanded our Management Board by appointing James Ryan as Chief Legal Officer (CLO), effective as of September 1, 2023. As CLO, James Ryan heads up our legal department and is responsible for developing and leading the Company’s corporate legal strategy to promote and protect BioNTech’s global operations. His current appointment to our Management Board will end on August 30, 2027.

The following table sets forth the names and functions of the current members of our Management Board, their ages as of December 31, 2023 and their terms:

Name	Age	Term Expires	Position
Prof. Ugur Sahin, M.D.	58	2026	Chief Executive Officer
Jens Holstein	60	2025	Chief Financial Officer
Sean Marett	58	2024 ⁽²⁾	Chief Business Officer and Chief Commercial Officer
Sierk Poetting, Ph.D.	50	2026	Chief Operating Officer
Ryan Richardson	44	2026	Chief Strategy Officer
James Ryan, Ph.D. ⁽¹⁾	48	2027	Chief Legal Officer
Prof. Özlem Türeci, M.D.	56	2025	Chief Medical Officer

⁽¹⁾ Appointed effective as of September 1, 2023.

⁽²⁾ Sean Marett will retire as planned from the Management Board of BioNTech as of June 30, 2024. He will continue as a specialist advisor to the Company at least until the end of the year 2024.

The business address of the members of our Management Board is the same as our business address: An der Goldgrube 12, D-55131 Mainz, Germany.

The following is a brief summary of the business experience of the members of our Management Board:

Prof. Ugur Sahin, M.D. co-founded BioNTech in 2008 and has served as our Chief Executive Officer since that time. He is a physician, immunologist and leader in the development of novel approaches to fight cancer and infectious diseases. Ugur Sahin is one of the world’s foremost experts on messenger ribonucleic acid (mRNA) medicines. He has

pioneered several fundamental breakthroughs enabling the development of mRNA vaccines and other types of immunotherapies. He initiated and oversaw “Project Lightspeed,” the historic development of the first mRNA vaccine for COVID-19, moving from lab and clinical testing to conditional approval within an unprecedented 11-month period. He also leads BioNTech’s research and development of neoantigen specific as well as non-neoantigen specific mRNA cancer vaccines, which can be individually tailored and produced on demand according to the profile of non-synonymous mutations identified by next-generation sequencing in patients’ tumors. Ugur Sahin is co-inventor of more than 500 filed patents applications and patents. His academic credentials include serving as a Full Professor in Translational Oncology & Immunology at Johannes Gutenberg University in Mainz, Germany, where he was the supervisor of more than 50 Ph.D. students. He also holds the role of Chairman of the Scientific Management Board of the Helmholtz Institute for Translational Oncology (HI-TRON). Based on his contributions to scientific discovery, Ugur Sahin has received numerous awards and recognitions, including the German Sustainability Award, the Mustafa Prize, and the German Cancer Award. He is married to Özlem Türeci.

Jens Holstein is our Chief Financial Officer. Prior to joining BioNTech in 2021, Jens was CFO of dual-listed MorphoSys AG (Nasdaq/FWB: MOR) where he was instrumental in building a fully integrated biopharmaceutical company. Before joining MorphoSys in 2011, Jens Holstein served in multiple CFO positions as well as general management roles within the Fresenius SE Group. He served as Regional CFO for the region EME (Europe/Middle East) and as Managing Director of Fresenius Kabi Deutschland GmbH. From 2006 to 2010, he was Regional CFO of Fresenius Kabi Asia Pacific Ltd., based in Hong Kong. Prior to this appointment, Jens Holstein was Managing Director of Fresenius ProServe GmbH, and CFO and Labor Director of the company’s subsidiary Wittgensteiner Kliniken AG. Earlier positions within Fresenius included General Manager of hospitalia care GmbH, Commercial Manager of the Projects & Service business unit of Fresenius AG and Commercial Manager of hospitalia international GmbH. Jens Holstein also spent several years in the consulting industry, including in M&A with positions in Frankfurt and London. Jens Holstein holds a Diploma in Business Administration from the University of Münster, Germany. He is also a non-executive member of the board of directors at global genomic diagnostics company Veracyte Inc.

Sean Marett is our Chief Business Officer and Chief Commercial Officer. He joined BioNTech in 2012. Prior to that, he worked in global strategic and regional marketing and sales roles at GlaxoSmithKline (NYSE: GSK) in the United States and Pfizer (NYSE: PFE) in Europe, before taking business development executive roles at Evotec (Nasdaq: EVO; FWB: EVT) and Lorantis. He has successfully executed complex licensing transactions with large pharmaceutical companies, negotiated M&A transactions and raised finance from investors. Sean Marett built and ran a contract clinical manufacturing organization with operations across Europe and the United States for over half a decade for the contract manufacturer NextPharma. Sean Marett has been Chairman of PHMR Ltd, a company specializing in market access and pharmaceutical reimbursement, since 2017. He previously held non-executive directorship of KWS BioTest Ltd (successfully sold to Charles River) from 2011 until 2018 and was a member of the investment committee of Mann BioInvest Ltd, a fund dedicated to biotechnology and pharmaceutical company investments from 2013 until 2016. He holds a BSc (Hons) in Biochemistry from Kings College London and an MBA from Manchester Business School.

Sierk Poetting, Ph.D. is our Chief Operating Officer. He joined BioNTech in September 2014 from Novartis (NYSE: NV), where he served in various positions from May 2012 to August 2014 as Vice President and Chief Financial Officer for the Sandoz Division in North America. Sierk Poetting started his career as a consultant with McKinsey & Company. A German citizen, Sierk Poetting holds a Master of Science in Optical Sciences from the University of Arizona and a Ph.D. in Physics from the Ludwig-Maximilians University in Munich.

Ryan Richardson is our Chief Strategy Officer. He brings more than 20 years of experience in the healthcare and finance industries to BioNTech. Ryan joined BioNTech in 2018 as Senior Vice President, Corporate Development & Strategy and was appointed to Chief Strategy Officer and a Member of the Management Board in 2020. Prior to joining BioNTech, Ryan Richardson was an Executive Director in the Global Healthcare Investment Banking team at J.P. Morgan in London, where he advised companies in the biotech and life sciences industry on cross-border M&A, equity and debt capital financings. Earlier in his career, Ryan Richardson worked as a Management Consultant to biopharmaceutical companies in the United States and Europe, focusing on a wide range of strategic and operational projects in the areas of commercial strategy, pricing and market access, new product planning, and R&D transformation. Ryan has also worked as a Health Economist at IMS Health in London. Ryan was the recipient of the 2018 Eisenhower Zhi Xing Fellowship to China, and the 2005-6 Robert R. Bosch Fellowship to Germany. Ryan Richardson holds an International MBA from the University of Chicago Booth School of Business, an MSc from the London School of Economics, and a BS in Biology from the University of Kansas.

James Ryan, Ph.D., is our Chief Legal Officer. He brings nearly 20 years of global legal and IP expertise in the pharmaceutical industry to BioNTech. James Ryan joined the Company in 2018 as General Counsel and Senior Vice

President Legal & IP and was appointed to Chief Legal Officer and a Member of the Management Board in 2023. He has guided BioNTech through a wide range of key business, IP and transactional activities, mergers and acquisitions, strategic collaborations and equity capital markets transactions, including the Company's IPO in 2019. James Ryan and his teams played a pivotal role in the successful development of the Pfizer-BioNTech COVID-19 vaccine, supporting every legal aspect of the program, its launch and commercialization. Prior to joining BioNTech, he established the legal group of GW Pharmaceuticals (NASDAQ: GWPH), where he also served as Head of Legal Affairs. Earlier in his career, James Ryan worked for a number of UK and U.S. law firms, including Special Counsel at Covington & Burling LLP, where he specialized in commercial and strategic transactions with a focus on companies in the life sciences sector. James has a Ph.D. in epigenetics from the University of St Andrews, is a member of the Law Society of England & Wales, and is a member of the Law Society of Ireland.

Prof. Özlem Türeci, M.D., Co-founder and Chief Medical Officer of BioNTech, is a physician, immunologist, and cancer researcher with translational and clinical experience. She has helped lead the discovery of cancer antigens, the development of mRNA-based individualized and off-the-shelf vaccine candidates and other types of immunotherapies which are currently in clinical development. Özlem Türeci leads the clinical development of BioNTech's "Project Lightspeed", the company's successful effort to develop and distribute an mRNA-based vaccine against COVID-19, a historic achievement completed in less than one year. Özlem Türeci previously served as CEO and Chief Medical Officer of Ganymed Pharmaceuticals AG, which she co-founded with Ugur Sahin and Christoph Huber. She is also a professor for Personalized Immunotherapy at the University Medical Center Mainz and the Helmholtz Institute for Translational Oncology Mainz (HI-TRON) and currently serves as President of the Association for Cancer Immunotherapy (CIMT) in Germany. She is a recipient of the German Sustainability Award, among other notable recognitions. Özlem Türeci is married to Ugur Sahin.

Supervisory Board (*Aufsichtsrat*)

In 2023, the term of office of the Supervisory Board members Ulrich Wandschneider, Christoph Huber, and Michael Motschmann, who were elected by the shareholders at the Annual General Meeting (AGM) on September 17, 2018, ended at the close of the Annual General Meeting on May 25, 2023. As part of the 2023 AGM, Ulrich Wandschneider and Michael Motschmann were re-elected as Supervisory Board members. In addition, Nicola Blackwood was appointed to our Supervisory Board. She succeeded Christoph Huber, who left the Supervisory Board after reaching the applicable retirement age limit. Ulrich Wandschneider's, Nicola Blackwood's and Michael Motschmann's current appointment to our Supervisory Board will end at the AGM in 2027.

The following table sets forth the names and functions of the members of our Supervisory Board during 2023, their ages as of December 31, 2023, their terms (which expire on the date of the relevant year's general shareholders' meeting) and their principal occupations outside of our Company:

Name	Age	Term Expires	Principal Occupation
Helmut Jeggle (Chair Supervisory Board)	53	2026	Managing partner and entrepreneurial venture capital investor of Salvia GmbH (Supervisory Board member 4SC AG, AiCuris AG, APK AG and Tonies SE)
Ulrich Wandschneider, Ph.D. (Deputy Chair Supervisory Board)	62	2027	Managing director of beebusy capital GmbH and independent consultant to companies in the lifescience and healthcare sector
Baroness Nicola Blackwood ⁽¹⁾	44	2027	Managing Director and Chairman of Oxford University Innovations Limited (Equity Partner, ReCode Health Ventures LLC, Board Trustee and Director of the Alan Turing Institute, Chair of the Board of Genomics England Limited)
Prof. Christoph Huber, M.D. ⁽²⁾	79	2023	Professor emeritus at the Johannes-Gutenberg University Mainz (Deputy Chair of the Supervisory Board Tirol Kliniken GmbH)
Prof. Anja Morawietz, Ph.D.	46	2026	Certified Public Accountant and Management Consultant, Professor of External Accounting and General Business Administration at the Nuremberg University of Applied Sciences Georg Simon Ohm
Michael Motschmann	66	2027	Member of the Management Board and head of equity investments of MIG Capital AG (Supervisory Board member AFFiRiS AG, APK AG, HMW-Emissionshaus AG and HMW-Innovations AG)
Prof. Rudolf Staudigl, Ph.D.	69	2026	Independent consultant (member of the Supervisory Board of TÜV Süd Aktiengesellschaft, member of the Supervisory Board of Groz-Beckert KG (Deputy Chair))

⁽¹⁾ Appointed effective as of May 25, 2023.

⁽²⁾ Supervisory Board member until May 25, 2023.

The business address of the members of our Supervisory Board is the same as our business address: An der Goldgrube 12, D-55131 Mainz, Germany.

The following is a brief summary of the prior business experience of the members of our Supervisory Board (including Christoph Huber, who left the Supervisory Board after reaching the applicable retirement age limit):

Helmut Jeggle has been Chair of our Supervisory Board since its foundation in 2008. He has a degree in business administration from the University of Applied Sciences in Neu-Ulm and an MBA (Master of Business Administration) from the Stuttgart Institute of Management and Technology. From 2000 to 2007, Helmut Jeggle held various positions at Hexal AG. From 2007 onwards, he was, among other things, in charge of Direct Investments at ATHOS KG, the family office of the Strüngmann family, from which he resigned as general partner (*Komplementär*) in April 2021. Since 2014, Helmut Jeggle has been Managing Director of Salvia GmbH, where he acts as an entrepreneurial venture capital investor. He is currently a member of two other supervisory boards of listed companies, including 4SC AG (ETR: VSC) and Tonies SE (ETR: TNIE).

Ulrich Wandschneider, Ph.D. has served as a member of our Supervisory Board since 2018. He has more than 20 years of experience in the healthcare sector as a manager in the operative business and as a member of boards and committees. He was a Partner at Arthur Andersen until 2002 and at Deloitte from 2002 to 2004 in the healthcare and life science sector for many years. From 2004 to 2016 Ulrich Wandschneider served as Chief Executive Officer first of Mediolan AG later of Asklepios Kliniken GmbH & Co. KGaA. In addition to BioNTech SE, he is part of the Supervisory

Board of Marienhaus GmbH, Chairman of the Board of Trustees of Oberberg GmbH, Chairman of the Advisory Board of Argentum Pflege Holding GmbH, Panorama Fachklinik GmbH and SmileEyes GmbH and a member of the Advisory Board of Creative Balloons GmbH.

Baroness Nicola Blackwood has served as a member of our Supervisory Board since May 25, 2023. She has been Chair of Genomics England since 2020 and Chair of Oxford University Innovation since 2021. She is a member of the House of Lords, the upper chamber of the Parliament of the United Kingdom (UK). Blackwood was elected Member of Parliament for Oxford West and Abingdon 2010 to 2017 and served as Minister for Innovation at the UK Department of Health and Social Care from 2016 to 2017 and 2019 to 2020 where she led on life sciences, NHS data and digital transformation and global health security. Among other roles, she was Chair of the technical regulator, the Human Tissue Authority, as well as a Chair of the UK House of Commons Science and Technology Select Committee and a member of the House of Lords Science and Technology Select Committee. Nicola Blackwood was educated at Trinity College of Music, London, St Anne's College, Oxford, and Emmanuel College, Cambridge.

Christoph Huber, M.D. is a co-founder of BioNTech and has served as a member of our Supervisory Board since 2008. Christoph Huber has more than 50 years of professional experience in hematology, oncology and translational immunology. He served as Chair of the Department of Hematology and Oncology at the Johannes-Gutenberg University Mainz from 1990 to 2009 and, since 2009, has served as Chair Emeritus of the Department of Hematology and Oncology. He was a co-founder of Ganymed Pharmaceuticals AG, now a subsidiary of Astellas. Christoph Huber is an executive board member of CIMT and a board member of Ci3. From 2018 to April 2019, He served as a member of the supervisory board of TRON. Christoph Huber earned his M.D. at the University of Innsbruck.

Prof. Anja Morawietz, Ph.D. has served as a member of our Supervisory Board since 2022. She has been a professor of external accounting and general business administration at the Nuremberg University of Applied Sciences Georg Simon Ohm since 2015. Her research areas are international and national accounting, current developments in corporate governance and sustainability reporting. She also works as a freelance auditor, particularly in audit-related consulting. Previously, she worked for ten years for auditing company KPMG AG, where she conducted audits of annual and consolidated financial statements and advised clients on accounting and regulatory issues. After training as a bank clerk at Norddeutsche Landesbank in Hanover, Anja Morawietz studied business administration at Goethe University in Frankfurt am Main, where she also completed her doctorate as an external doctoral candidate.

Michael Motschmann has served as a member of our Supervisory Board since 2008. He co-founded MIG Verwaltungs AG, or MIG, in 2004, where he serves on the Management Board and as Head of Equity Investments. In his role with MIG, Michael Motschmann currently serves on the supervisory boards of several private portfolio companies.

Prof. Rudolf Staudigl, Ph.D. has served as a member of our Supervisory Board since 2022. He studied chemistry at Ludwig Maximilian University of Munich, obtaining his Ph.D. (Dr. rer. nat) in 1981. After postdoctoral research at Harvard University (Cambridge, USA) and Ludwig Maximilian University, he joined Wacker Chemitronic in 1983. Mr. Staudigl became Vice President of Operations at Wacker Siltronic Corporation (Portland, Oregon, USA) in 1989 and President a year later. He joined the Executive Board of Wacker Chemitronic in 1993. In 1995, Rudolf Staudigl was appointed to the Executive Board of Wacker Chemie. In May 2008, Rudolf Staudigl was appointed President & CEO of Wacker Chemie AG. He currently serves on various supervisory boards.

B. Compensation

Compensation of Our Supervisory Board Members

The compensation system of our Supervisory Board as included in our Articles of Association is structured as 100% fixed compensation. The compensation system for Supervisory Board members for 2023 was retained from 2022.

Pursuant to Sec. 113 para. 3 AktG, as amended by the Act Implementing the Second Shareholder Rights Directive, the Annual General Meeting of a listed company must pass a resolution on the compensation of the members of the Supervisory Board at least every four years.

The members of the Supervisory Board receive an annual compensation of €70,000, the Chair €210,000 and the Vice Chair €105,000. The Chair of the Audit Committee receives an additional annual compensation of €30,000. The respective

Chair of another committee receives an additional annual compensation of €15,000. An ordinary committee member receives an additional annual remuneration of €5,000 per committee.

All members of the Supervisory Board are reimbursed for their expenses.

<i>in thousands €</i>	Helmut Jegg	Ulrich Wandschneider, Ph.D.	Baroness Nicola Blackwood⁽¹⁾	Prof. Christoph Huber, M.D.⁽²⁾	Prof. Anja Morawietz, Ph.D.	Michael Motschmann	Prof. Rudolf Staudigl, Ph.D.
	<i>Chair</i>	<i>Vice Chair</i>					
Base Compensation							
2023	210	105	42	28	70	70	70
2022	210	105	—	70	35	70	35
Committee Compensation							
2023	16	9	4	2	35	10	20
2022	15	35	—	10	—	25	—
Total							
2023	226	114	46	30	105	80	90
2022	225	140	—	80	35	95	35

⁽¹⁾ Nicola Blackwood was appointed to the Supervisory Board by the Annual General Meeting on May 25, 2023.

⁽²⁾ Christoph Huber served as a member of our Supervisory Board from 2008 and left the Supervisory Board on May 25, 2023 after reaching the retirement age limit.

Members of the Supervisory Board who are only members of the Supervisory Board or committees, or who chair or vice-chair the Supervisory Board or the Audit Committee or another committee, for part of the financial year receive the respective compensation on a pro-rata basis.

Hence, the compensation of the Supervisory Board members who either left or joined in 2023, namely Christoph Huber and Nicola Blackwood, was paid on a pro-rata basis with respect to their departure or appointment at our AGM on May 25, 2023. In addition, compensation was paid to the members of the Product Committee with effect from the date of its establishment as of October 1, 2023.

If the reimbursement of expenses or the compensation is subject to value-added tax, the value-added tax shall be paid in addition.

The Supervisory Board members are included in our D&O liability insurance and are co-insured at our expense.

The current appointments of our Supervisory Board will end with the Annual General Meeting during the respective year set forth below:

- Helmut Jegg: 2026
- Ulrich Wandschneider: 2027
- Nicola Blackwood: 2027
- Anja Morawietz: 2026
- Michael Motschmann: 2027
- Rudolf Staudigl: 2026

Compensation of the Members of Our Management Board

We have entered into agreements with all current members of our Management Board.

We believe that the agreements between us and the members of our Management Board provide for payments and benefits (including upon termination of employment) that are in line with customary market practice.

The following sets forth the termination dates of the current service agreements of our Management Board:

- Prof. Ugur Sahin, M.D.: December 31, 2026
- Jens Holstein: June 30, 2025
- Sean Marett: December 31, 2024
- Sierk Poetting, Ph.D.: November 30, 2026
- Ryan Richardson: December 31, 2026
- James Ryan, Ph.D.: August 31, 2027
- Prof. Özlem Türeci, M.D.: May 31, 2025

Effective January 1, 2023, Ugur Sahin's annual fixed compensation was increased to €700,000 from €360,000 as part of an annual compensation review to ensure competitive compensation comparable to that of companies in a comparable sector and relevant peer group. Jens Holstein's effective annual fixed compensation was €550,000 during each of the years ended December 31, 2023 and 2022. Effective April 1, 2022, Sean Marett's annual fixed compensation was increased from €400,000 to €550,000. Hence, during the years ended December 31, 2023 and 2022, his effective annual fixed compensation amounted to €550,000 and €512,500, respectively. Sierk Poetting's effective annual fixed compensation amounted to €550,000, respectively, during the years ended December 31, 2023 and 2022. Effective as of his appointment to the Management Board as of September 1, 2023, James Ryan's annual fixed compensation was €550,000. His compensation is partly paid in the U.K. (in GBP) by the Company's subsidiary, BioNTech UK Limited, and partly in Germany (in Euro). During the year ended December 31, 2023, his effective annual fixed compensation as a Management Board member amounted to €183,333. Ryan Richardson's annual fixed compensation was increased from €340,000 to €550,000 leading to the respective effective annual fixed compensation during the years ended December 31, 2023 and 2022. Effective March 1, 2022, Özlem Türeci's annual fixed compensation was increased from €360,000 to €550,000. Hence, during the years ended December 31, 2023 and 2022, her effective annual fixed compensation amounted to €550,000 and €518,333, respectively. The increase in the fixed compensation payable to Sean Marett, Ryan Richardson and Özlem Türeci increased to €550,000 to align with the fixed compensation payable to Jens Holstein under his 2021 service agreement, which was considered necessary and in the Company's interest to retain our existing Management Board members. All of the Management Board members' activities for BioNTech Group companies are compensated by their base compensation of €550,000 and in the case of Ugur Sahin, €700,000. Management Board's service agreements also include a short-term incentive compensation component, which is an annual performance-related bonus for the years of their respective service periods. During the year ended December 31, 2022, the maximum short-term incentive compensation for each of Ugur Sahin, Jens Holstein, Sean Marett, Sierk Poetting, Ryan Richardson and Özlem Türeci was €180,000; €300,000; €300,000; €170,000; and €300,000, respectively, which, considering the 2022 target achievement of 85%, led to respective annual bonus amounts of €153,000; €255,000; €255,000; €255,000; €144,500; and €255,000. Following the extension of their respective service agreements and in line with the changes in their annual fixed compensation, the maximum short-term incentive compensation for Ugur Sahin and Ryan Richardson was increased to €350,000 and €300,000 respectively. Following his appointment to the Management Board as of September 1, 2023, the maximum short-term compensation for James Ryan was defined on a pro-rata basis and amounted to €100,000 for the year ended December 31, 2023. Based on the 2023 target achievement of 90%, the annual bonus amounts for Ugur Sahin, Jens Holstein, Sean Marett, Sierk Poetting, Ryan Richardson, James Ryan and Özlem Türeci for the year ended December 31, 2023 amounted to €315,000; €270,000; €270,000; €270,000; €270,000; €90,000; and €270,000, respectively.

The payout amount of the short-term incentive compensation depends on the achievement of certain financial and non-financial performance criteria of the Group in a particular financial year, which goals are set uniformly for all members of the Management Board. The Supervisory Board exercises reasonable discretion in determining whether such criteria have been achieved. 50% percent of the compensation is paid following determination of the actual achievement of the performance targets (first installment), with the remaining amount payable one year after such determination, subject to adjustment relative to the performance of the price of the American Depositary Shares representing our ordinary shares during that year (second installment).

Our Management Board's service agreements provide for long-term incentive compensation (Management Board Grant - LTI) through an annual grant of options to acquire BioNTech shares during their respective service periods. The options granted each year are subject to the terms and conditions of the respective authorizations of the Annual General Meeting creating our Employee Stock Ownership Plan (ESOP) and the applicable option agreements thereunder. During the year ended December 31, 2022, the number of options granted to Ugur Sahin, Jens Holstein, Sean Marett, Sierk Poetting, Ryan Richardson and Özlem Türeci was calculated based on a target value of €750,000; €550,000; €550,000; €550,000; €280,000; and €550,000, respectively. Beginning on January 1, 2023, the target for the number of options to be granted each year for Ugur Sahin and Ryan Richardson was increased to a value of €1,050,000 and €550,000, respectively, as part of an annual compensation review to ensure competitive compensation. As a result, the number of options granted to Ugur Sahin, Jens Holstein, Sean Marett, Sierk Poetting, Ryan Richardson and Özlem Türeci was calculated based on a target value of €1,050,000; €550,000; €550,000; €550,000; €550,000; and €550,000, respectively. The service agreement with James Ryan provides that granted options will generally be calculated based on a target value of €550,000. However, as the annual grant is generally made in the first half of the year, no LTI was granted for the period from his appointment on September 1, 2023 to December 31, 2023.

Taking the requirements of Sec. 87a para. 1 AktG into account, the Supervisory Board adopted a compensation system for the members of the Management Board on May 7, 2021. The compensation system was approved by the Annual General Meeting on June 22, 2021 and has become effective in connection with the entry into or extension of service agreements or the initiation of specific compensation components.

The comprehensive compensation system as approved by the Annual General Meeting on June 22, 2021 includes specific provisions with respect to benefits upon termination and is available online on our website at www.biontech.com. The information and other content appearing on our website are not incorporated by reference into this Annual Report and our website address is included in this report as an inactive textual reference only.

During the years ended December 31, 2023, and 2022, the aggregated remuneration for members of our Management Board amounted to 8.3 million and 15.0 million, respectively.

<i>in thousands €</i>	Prof. Ugur Sahin, M.D.	Jens Holstein⁽²⁾	Sean Marett	Sierk Poetting, Ph.D.	Ryan Richardson	James Ryan, Ph.D.⁽³⁾	Prof. Özlem Türeci, M.D.
Fixed compensation⁽¹⁾							
2023	700	550	550	550	550	183	550
2022	360	550	513	550	340	—	518
Fringe benefits⁽⁴⁾							
2023	6	5	12	5	26	—	—
2022	6	7	8	4	27	—	—
Short-term incentive – first installment							
2023	158	135	135	135	135	45	135
2022	77	128	128	128	72	—	128
Short-term incentive – second installment⁽⁵⁾							
2023	291	39	56	90	247	156	74
2022	3	188	141	235	4	—	183
Other variable compensation							
2023	—	600 ⁽⁷⁾	—	—	—	180 ⁽⁶⁾	—
2022	—	—	60	—	—	—	—
Share-based payments (incl. long-term incentive)⁽⁸⁾							
2023	1,901	(10)	(620)	41	452	284	55
2022	5,866	863	1,507	1,550	69	—	809
Total							
2023	3,056	1,319	133	821	1,410	848	814
2022	6,312	1,736	2,357	2,467	512	—	1,638

⁽¹⁾ For James Ryan, a part of the fixed compensation was paid by BioNTech UK Limited, a subsidiary of BioNTech SE. Approximately 30% of his total compensation is attributable to his position as a member of the Management Board and approximately 70% is attributable to his position as a director of BioNTech UK Limited.

⁽²⁾ Jens Holstein was appointed to the Management Board as Chief Financial Officer (CFO) effective as of July 1, 2021. As of his appointment, the Supervisory Board granted Jens Holstein a one-time signing bonus €800,000 in the form of 4,246 phantom shares which are included in the share-based payments amounts. The phantom shares vest in four equal installments on July 1 of 2022, 2023, 2024, and June 30, 2025 but will only be settled in cash on July 1, 2025. The cash payment is subject to an effective settlement closing price cap. This means that the settlement closing price shall effectively be adjusted to ensure that the current price of an ADS as of the settlement date does not exceed 800% of the closing price applied when the award was initially granted. In addition, the total cash payment under the award shall not exceed €6.4 million.

⁽³⁾ James Ryan was appointed to the Management Board as Chief Legal Officer (CLO) effective as of September 1, 2023. His compensation for the year ended December 31, 2023 was granted on a pro-rata basis.

⁽⁴⁾ Includes social security, health and additional insurance, company bike and travel expenses. Other fringe benefits, e.g., costs for security services, which are integral to the performance of business duties, are not included in the amount.

⁽⁵⁾ The fair value of the second installment of the short-term incentive compensation which has been classified as a cash-settled share-based payment arrangement was determined pursuant to the regulations of IFRS 2 “Share-based Payments.” This table shows the pro-rata share of personnel expenses for the respective financial year that are recognized over the award’s vesting period beginning as of the service commencement date (date when entering or renewing service agreements) until each separate determination date and are remeasured until settlement date.

- (6) During the year ended December 31, 2023, as part of his appointment to the Management Board, James Ryan received a one-time signing cash payment in the amount of €180,000. The one-time signing cash payment provided compensation in lieu of participation in the LTI 2023 program, which was allocated before his appointment, and a pro-rata allocation for 2023 would not have been permitted under our current AGM authorizations, as ESOPs may only be issued within the first six months of each calendar year. Of this payment, James Ryan shall use 50% net of costs and expenses to purchase BioNTech shares on or before August 31, 2024 to further strengthen his long-term commitment.
- (7) During the year ended December 31, 2023, upon the recommendation of the Compensation, Nomination and Corporate Governance Committee, the Supervisory Board approved a special payment in the gross amount of €600,000 to Jens Holstein. The special payment was made to honor Jens Holstein's contribution to the extraordinary financial performance of BioNTech and recognize his efforts to strengthen the Company's long-term financial performance. Of this payment, Jens Holstein used €150,000 net of costs and expenses to purchase 1,620 BioNTech shares during the year ended December 31, 2023 to further strengthen his long-term commitment.
- (8) The fair value of the share-based payments was determined pursuant to the regulations of IFRS 2 "Stock-based Payments." This table shows the pro-rata share of personnel expenses resulting from stock-based compensation for the respective financial year. It includes the share-based payment arrangements explained in footnote (1) and (2) and those explained in "Share-Based Payment Arrangements" in Note 16 to our consolidated financial statements included elsewhere in this Annual Report.

The table below provides an overview of the (phantom) share options and other share-based payment instruments granted to our Management Board which are outstanding as of December 31, 2023 - excluding future grants:

	Grant Date / Allocation Date	Number of Ordinary Shares Underlying Share Options / Number of Phantom Share Options ⁽¹⁾	Option Exercise Price (€) ⁽¹¹⁾	Earliest Option Exercise Date ⁽⁹⁾	Option Expiration Date	Name of the Program
Prof. Ugur Sahin, M.D.	10/9/2019 ⁽²⁾	4,374,963	13.57	10/9/2023	10/9/2029	CEO Grant 2019
	2/13/2020 ⁽³⁾	97,420	27.86	2/13/2024	2/13/2030	LTI 2020 ⁽¹⁰⁾
	5/12/2021 ⁽⁴⁾	17,780	167.63	5/12/2025	5/12/2031	LTI 2021 ⁽¹⁰⁾
	5/31/2022 ⁽⁵⁾	19,997	137.65	5/31/2026	5/31/2032	LTI 2022 ⁽¹⁰⁾
	5/20/2023 ⁽⁶⁾	38,506	103.12	5/20/2027	5/20/2033	LTI 2023 ⁽¹⁰⁾
Jens Holstein	5/17/2021 ⁽⁴⁾	6,463	169.08	5/17/2025	5/17/2031	LTI 2021
	7/1/2021 ⁽⁸⁾	4,246	n/a ⁽⁸⁾	7/1/2025 ⁽⁸⁾	n/a ⁽⁸⁾	Signing Bonus
	5/31/2022 ⁽⁵⁾	14,664	137.65	5/31/2026	5/31/2032	LTI 2022 ⁽¹⁰⁾
	5/20/2023 ⁽⁶⁾	18,416	103.12	5/20/2027	5/20/2033	LTI 2023 ⁽¹⁰⁾
Sean Marett	11/15/2018	—	10.14	11/15/2022	11/15/2026	ESOP 2018
	2/13/2020 ⁽³⁾	7,112	27.86	5/12/2025	5/12/2031	LTI 2020 ⁽¹⁰⁾
	5/12/2021 ⁽⁴⁾	14,664	137.65	5/31/2026	5/31/2032	LTI 2021 ⁽¹⁰⁾
	5/31/2022 ⁽⁵⁾	14,664	137.65	31/05/2026	5/31/2032	LTI 2022 ⁽¹⁰⁾
	5/20/2023 ⁽⁶⁾	18,416	103.12	20/05/2027	5/20/2033	LTI 2023 ⁽¹⁰⁾
Sierk Poetting, Ph.D.	2/13/2020 ⁽³⁾	38,968	27.86	2/13/2024	2/13/2030	LTI 2020 ⁽¹⁰⁾
	5/12/2021 ⁽⁴⁾	7,112	167.63	5/12/2025	5/12/2031	LTI 2021 ⁽¹⁰⁾
	5/31/2022 ⁽⁵⁾	14,664	137.65	5/31/2026	5/31/2032	LTI 2022 ⁽¹⁰⁾
	5/20/2023 ⁽⁶⁾	18,416	103.12	5/20/2027	5/20/2033	LTI 2023 ⁽¹⁰⁾
Ryan Richardson	2/13/2020 ⁽³⁾	33,772	27.86	2/13/2024	2/13/2030	LTI 2020 ⁽¹⁰⁾
	5/12/2021 ⁽⁴⁾	6,163	167.63	5/12/2025	5/12/2031	LTI 2021 ⁽¹⁰⁾
	5/31/2022 ⁽⁵⁾	7,465	137.65	5/31/2026	5/31/2032	LTI 2022 ⁽¹⁰⁾
	5/20/2023 ⁽⁶⁾	18,416	103.12	5/20/2027	5/20/2033	LTI 2023 ⁽¹⁰⁾
James Ryan, Ph.D.⁽⁷⁾	12/15/2020	1,163	n/a	12/15/2024	n/a	LTI 2020 (EEP)
	12/10/2021	313	n/a	12/10/2025	n/a	LTI 2021 (EEP)
	12/9/2022	740	n/a	12/9/2026	n/a	LTI 2022 (EEP)
	12/8/2023	750	n/a	12/8/2027	n/a	LTI 2023 (EEP)
Prof. Özlem Türeci, M.D.	2/13/2020 ⁽³⁾	38,968	27.86	2/13/2024	2/13/2030	LTI 2020 ⁽¹⁰⁾
	5/12/2021 ⁽⁴⁾	7,112	167.63	5/12/2025	5/12/2031	LTI 2021 ⁽¹⁰⁾
	5/31/2022 ⁽⁵⁾	14,664	137.65	5/31/2026	5/31/2032	LTI 2022 ⁽¹⁰⁾
	5/20/2023 ⁽⁶⁾	18,416	103.12	5/20/2027	5/20/2033	LTI 2023 ⁽¹⁰⁾

⁽¹⁾ The 18-for-1 stock split of our ordinary shares, which became effective on September 18, 2019 upon registration with the commercial register (*Handelsregister*) is reflected in share amounts granted in advance.

- (2) Options vested in four equal installments on October 9 of 2020, 2021, 2022 and 2023. With the final installment vesting in 2023, the entire award became exercisable. As Ugur Sahin did not exercise in 2023, the options remain exercisable and can only be exercised during the exercise windows as defined by our ESOP.
- (3) Options vested in four equal installments on February 13 of 2021, 2022, 2023 and 2024, and are now exercisable following the expiry of the waiting period on February 13, 2024 and can only be exercised during the exercise windows as defined by our ESOP.
- (4) Options were issued as phantom share options and vest in four equal installments on May 12 of 2022, 2023, 2024 and 2025 for all Management Board members except Jens Holstein, and in the case of Jens Holstein, vest in four equal installments on May 17 of 2022, 2023, 2024 and 2025. The options will not become exercisable before the expiry of the waiting period on May 12, 2025 and May 17, 2025, respectively, and can only be exercised during the exercise windows as defined by our ESOP.
- (5) Options were issued as phantom share options and vest in four equal installments on May 31 of 2023, 2024, 2025 and 2026 for all Management Board members. The options will not become exercisable before the expiry of the waiting period on May 31, 2026 and can only be exercised during the exercise windows as defined by our ESOP.
- (6) Options vest in four equal installments on May 20 of 2024, 2025, 2026 and 2027. The options will not become exercisable before the expiry of the waiting period on May 20, 2027 and can only be exercised during the exercise windows as defined by our ESOP.
- (7) As James Ryan was not part of the Management Board at the time the 2023 LTI award was allocated, he did not receive any options under the ESOP. Prior to his appointment to the Management Board, RSUs were granted to him under the BioNTech 2020 Employee Equity Plan (EEP). RSUs issued under the LTI 2020 (EEP), LTI 2021 (EEP), LTI 2022 (EEP) and LTI 2023 (EEP) programs vest annually in equal installments over four years commencing in December 2020, December 2021, December 2022 and December 2023 respectively and will be settled after a waiting period of four years.
- (8) In connection with Jens Holstein's appointment to the Management Board as Chief Financial Officer (CFO) on July 1, 2021, the Supervisory Board granted him a one-time signing bonus of €800,000 in the form of 4,246 phantom shares. The phantom shares vest in four equal installments on July 1 of 2022, 2023, 2024 and June 30, 2025 but will only be settled in cash on July 1, 2025. The cash payment is subject to an effective settlement closing price cap. This means that the settlement closing price shall effectively be adjusted to ensure that the current price of an ADS as of the settlement date does not exceed 800% of the cash payment, which in respect of all phantom shares shall not exceed €6.4 million.
- (9) Indicates end of the respective waiting periods, additional restrictions with respect to exercise windows may apply.
- (10) Management Board Grant (Long-Term Incentive) in the respective years.
- (11) All options are subject to an effective exercise price cap. This means that the exercise price shall effectively be adjusted to ensure that the current price of an ADS as of the exercise does not exceed 800% of the exercise price. With respect to the ESOP 2018 Program and the CEO Grant 2019, the maximum economic benefit receivable in respect of any exercised option is capped at \$240.00, with the effective exercise price being capped at a Euro amount equivalent to \$30.00. With respect to the LTI 2020, the maximum economic benefit receivable in respect of any exercised option is capped at \$246.24, with the effective exercise price being capped at a Euro amount equivalent to \$30.78. With respect to the phantom share options issued under the LTI 2021 and 2022 as well as the options issued under the LTI 2023 programs, the maximum compensation that the Management Board members are entitled to receive under such programs, together with other compensation components received by each such board member in the respective grant year, shall not exceed €20.0 million for Ugur Sahin as Chief Executive Officer (CEO) and €10.0 million for all other Management Board members.

Share-Based Payment Arrangements

Management Board Grant (Long-Term Incentive)

Our Management Board's service agreements provide for long-term incentive compensation (Management Board Grant - LTI) through an annual grant of options to acquire BioNTech shares during their respective service periods.

The allocation of the number of issued options in 2020 occurred in February 2020. In May 2021 and May 2022, the Management Board received phantom options equivalent to the number of options the Management Board members would have been entitled to receive for 2021 and 2022. During 2023, options were granted in May 2023.

For the awards allocated as of February 13, 2020; May 12, 2021; May 17, 2021; May 31, 2022 and May 20, 2023, the exercise prices are \$30.78 (€27.86); \$185.23 (€167.63); \$186.83 (€169.08); \$152.10 (138) and \$113.94 (€103.12) respectively (all amounts calculated as of December 31, 2023 using the foreign exchange rate as published by the German Central Bank (*Deutsche Bundesbank*)).

All options are subject to an effective exercise price cap, which means that the exercise price shall be adjusted to ensure that the current price of an ADS as of the exercise date does not exceed 800% of the exercise price. With respect to the LTI 2020, the maximum economic benefit receivable in respect of any exercised option is capped at \$246.24, with the effective exercise price being capped at a Euro amount equivalent to \$30.78. With respect to the phantom share options

issued under the LTI 2021 and 2022 as well as the options issued under the LTI 2023 programs, the maximum compensation that the Management Board members are entitled to receive under such programs, together with other compensation components received by each such board member in the respective grant year, shall not exceed €20.0 million for Ugur Sahin as Chief Executive Officer (CEO) and €10.0 million for all other Management Board members.

The options vest annually in equal installments over four years commencing on the first anniversary of the allocation date and become exercisable four years after the allocation date. The vested options can only be exercised if each of the following performance criteria has been achieved: (i) at the time of exercise, the current price is equal to or greater than the threshold amount (that is, the exercise price, provided that such amount increases by seven percentage points on each anniversary of the allocation date); (ii) at the time of exercise, the current price is at least equal to the target price (that is, (a) for the twelve-month period starting on the fourth anniversary of the allocation date, \$8.5 billion divided by the total number of the ordinary shares outstanding immediately following the initial public offering (other than ordinary shares owned by BioNTech), and (b) for each twelve-month period starting on the fifth or subsequent anniversary of the allocation date, 107% of the target share price applicable for the prior twelve-month period); and (iii) the closing price for the fifth trading day prior to the start of the relevant exercise window is higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index or a comparable successor index as of such time is higher than such index was as of the last trading day before the allocation date. Following the expiry of the waiting period, option rights may be exercised during the exercise windows as set out in the ESOP agreement. The option rights can be exercised up to ten years after the allocation date. If they have not been exercised by that date, they will be forfeited without compensation.

Chief Executive Officer Grant

In September 2019, we granted Ugur Sahin an option to purchase 4,374,963 of our ordinary shares, subject to his continuous employment with us. The exercise price per share of each option is \$15.00 (€13.57), being the public offering price from our initial public offering converted into Euros as of December 31, 2023, and which is subject to the effective exercise price cap and the maximum cap mechanism. Under the effective exercise price cap, the exercise price shall be adjusted to ensure that the current price of an ADS as of the exercise date does not exceed 800% of the exercise price. Under the maximum cap mechanism, the maximum economic benefit receivable in respect of any exercised option is capped at \$240, with the effective exercise price being capped at a Euro amount equivalent to \$30.00. Under this CEO Grant, the options vested annually in equal installments over four years commencing on the first anniversary of our initial public offering.

The vested option rights can only be exercised if and to the extent that each of the following performance criteria has been achieved: (i) at the time of exercise, the current price is equal to or greater than the threshold amount (that is, the exercise price, provided that such amount increases by seven percentage points on each anniversary of the allocation date); (ii) at the time of exercise, the current price is at least equal to the target price (that is, (a) for the twelve-month period starting on the fourth anniversary of the allocation date, \$8.5 billion divided by the total number of the shares outstanding immediately following the initial public offering (other than shares owned by us), and (b) for each twelve-month period starting on the fifth or subsequent anniversary of the allocation date, 107% of the target share price applicable for the prior twelve-month period); and (iii) the closing price for the fifth trading day prior to the start of the relevant exercise window is higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index or a comparable successor index as of such time is higher than such index was as of the last trading day before the allocation date. Following the expiry of the waiting period, option rights may be exercised during the exercise windows as defined by our ESOP. The option rights can be exercised up to ten years after the allocation date. If they have not been exercised by that date, they will be forfeited without compensation.

On October 9, 2023, with the final installment vesting, all 4,374,963 options became exercisable under the rules of the ESOP and the ESOP agreement. During the year ended December 31, 2023, no options were exercised.

Employee Stock Ownership Plan

Based on an authorization of the general meeting on August 18, 2017, we established a share option program under which we granted selected employees options to receive our shares. The program is designed as an Employee Stock Ownership Plan, or ESOP. We offered participants a certain number of option rights by their explicit acceptance of an option rights agreement. The exercise of option rights in accordance with the agreement gives the participants the right to obtain shares against payment of the exercise price. With respect to the Management Board members serving at the time of allocation, the options are subject to the effective exercise price cap and maximum cap mechanisms. Under the exercise

price cap, the exercise price shall be adjusted to ensure that the current price of an ADS as of the exercise date does not exceed 800% of the exercise price. Under the maximum cap mechanism, the maximum economic benefit receivable in respect of any exercised option, is capped at \$240, with the effective exercise price being capped at a Euro amount equivalent to \$30.00. Under the ESOP, the option rights (other than Özlem Türecci's, and Ryan Richardson's options) fully vest after four years and can be exercised if: (i) the waiting period of four years has elapsed; and (ii) at the time of exercise, the average closing price of the shares of the Company or the average closing price of the right or certificate to be converted into an amount per share on the previous ten trading days preceding the exercise of the option right exceeds the strike price by a minimum of 32%, with this percentage increasing by eight percentage points as of the fifth anniversary of the respective issue date and as of each subsequent anniversary date. Following the expiry of the waiting period, option rights may be exercised within a period of four weeks from the date of the Annual General Meeting or the publication of the annual financial statements, the semi-annual report or our most recent quarterly report or interim report (exercise windows). The option rights can be exercised up to eight years after the allocation date. If they have not been exercised by that date, they will be forfeited without compensation.

By way of a shareholders' resolution of the general meeting on August 19, 2019, the authorization to issue such option rights was amended such that, in order for the options to be exercisable, the average closing price of the Company's shares or the average closing price of the right or certificate to be converted into an amount per share on the ten trading days immediately preceding the exercise must exceed the strike price by a minimum of 28%, with this percentage increasing by seven percentage points as of the fifth anniversary of the issue date and as of each subsequent anniversary date. Furthermore, in addition to the aforementioned requirements, the exercise is only possible if the share price (calculated by reference to the price of the ordinary share underlying the ADS) has performed similar to or better than the Nasdaq Biotechnology Index. The changes made do not affect option rights already issued.

In September 2022, the Supervisory Board determined the ESOP settlement by the delivery of treasury shares (in the form of ADSs) equal to the net value of the exercised option rights after deduction of (i) the exercise price and (ii) the applicable wage taxes (including solidarity surcharge thereon and church tax, if applicable) and social security contributions resulting from such exercise. The settlement was applied during the exercise windows in 2022 and 2023.

Out of the 5,152,410 option rights granted to our Management Board under the ESOP 2018 program 4,921,630 options were exercised during the year ended December 31, 2022. The remaining 230,780 option rights were exercised by Sean Marett in May 2023. As of December 31, 2023, no further options issued to our Management Board members are outstanding.

C. Board Practices

Two-Tiered Board Structure

We are a European public company with limited liability (*Societas Europaea* or SE) (also referred to as European stock corporation, and in the official terminology of the European legislation referred to as European public limited-liability company), having its seat in Germany. We have chosen to have a two-tiered SE structure. Hence, our corporate bodies are the Management Board (*Vorstand*), the Supervisory Board (*Aufsichtsrat*) and the shareholders' meeting (*Hauptversammlung*). Our Management and Supervisory Boards are entirely separate, and, as a rule, no individual may simultaneously be a member of both boards.

Our Management Board is responsible for the day-to-day management of our business in accordance with applicable laws, our Articles of Association (*Satzung*) and the Management Board's internal rules of procedure (*Geschäftsordnung*). Our Management Board represents us in our dealings with third parties.

The principal function of our Supervisory Board is to supervise our Management Board. The Supervisory Board is also responsible for appointing and removing the members of our Management Board, representing us in connection with transactions between a current or former member of the Management Board and us, and granting approvals for certain significant matters.

Our Management Board and our Supervisory Board are solely responsible for and manage their own areas of competency (*Kompetenztrennung*); therefore, neither board may make decisions that, pursuant to applicable law, our Articles of Association or the internal rules of procedure are the responsibility of the other board. Members of both boards

owe a duty of loyalty and care to us. In carrying out their duties, they are required to exercise the standard of care of a prudent and diligent businessperson. If they fail to observe the appropriate standard of care, they may become liable to us.

In carrying out their duties, the members of both boards must take into account a broad range of considerations when making decisions, including our interests and the interests of our shareholders, employees, creditors and, to a limited extent, the general public, while respecting the rights of our shareholders to be treated on equal terms. Additionally, the Management Board is responsible for implementing an appropriate and effective internal control system and risk management system with regard to the scope of business activities and the risk situation of the Company.

Our Supervisory Board has comprehensive monitoring responsibilities. To ensure that our Supervisory Board can carry out these functions properly, our Management Board must, among other duties, regularly report to our Supervisory Board regarding our current business operations and future business planning (including financial, investment and personnel planning). In addition, our Supervisory Board or any of its members is entitled to request special reports from the Management Board on all matters regarding the Company, our legal and business relations with affiliated companies and any business transactions and matters at such affiliated companies that may have a significant impact on our position at any time.

Under German law, our shareholders have, as a general rule, no direct recourse against the members of our Management Board or the members of our Supervisory Board in the event that they are believed to have breached their duty of loyalty and care to us. Apart from when we are unable to fulfill our third party obligations, tortious conduct to board members or other special circumstances, only we have the right to claim damages against the members of our two boards.

We may waive these claims to damages or settle these claims only if at least three years have passed since a claim associated with any violation of a duty has arisen and only if our shareholders approve the waiver or settlement at a shareholders' meeting with a simple majority of the votes cast, provided that no shareholders who in the aggregate hold one-tenth or more of our share capital oppose the waiver or settlement and have their opposition formally recorded in the meeting's minutes.

Supervisory Board

German law requires that the Supervisory Board consists of at least three members, while a company's articles of association may stipulate a certain higher number. Our Supervisory Board currently consists of six members.

As we are not subject to co-determination, the members of our Supervisory Board are all elected by the shareholders' meeting in accordance with the provisions of the SE Regulation and the German Stock Corporation Act (*Aktiengesetz*). German law does not require the majority of our Supervisory Board members to be independent and neither our Articles of Association (*Satzung*) nor the rules of procedure for our Supervisory Board provide otherwise. As per our Supervisory Board's assessment, an appropriate number of shareholder representatives on the Supervisory Board (i.e. the entire Supervisory Board) are independent if the Supervisory Board has two independent members. The Supervisory Board considers Helmut Jeggle and Michael Motschmann to be independent irrespective of the fact that they will soon have been members of the Supervisory Board for a period of more than 14 years. As stated in the declaration to the German Corporate Governance Code, or the Corporate Governance Code, (*Entsprechenserklärung*) published by the Company on February 27, 2024 pursuant to Section 161 para. 1 of the German Stock Corporation Act (*Aktiengesetz*), which in accordance with the Corporate Governance Code is issued in connection with the Declaration pursuant to Section 315d in conjunction with Section 289f of the German Commercial Code (HGB), the length of membership does not give rise to any fears of material conflicts of interest on the part of the members of the Supervisory Board and therefore does not stand in the way of their independence. However, the rules of procedure for our Supervisory Board provide that the Supervisory Board should have an independent member with expertise in the field of accounting, internal control processes and auditing. Ulrich Wandschneider, Anja Morawietz, Michael Motschmann and Rudolf Staudigl fulfill this role.

Under European law, a member of a supervisory board of an SE may be elected for a maximum term to be specified in the articles of association, which must not exceed six years. Re-election, including repeated re-election, is permissible. The shareholders' meeting may specify a term of office for individual members or all of the members of our Supervisory Board which is shorter than the standard term of office and, subject to statutory limits, may set different start and end dates for the terms of members of our Supervisory Board. Our Articles of Association provide for a term of approximately five years, depending on the date of the annual general shareholders' meeting in the year in which the term of the relevant member is to expire.

The shareholders' meeting may, at the same time as it elects the members of the Supervisory Board, elect one or more substitute members. The substitute members replace members who cease to be members of our Supervisory Board and take their place for the remainder of their respective terms of office. Currently, no substitute members have been elected or have been proposed to be elected.

Members of our Supervisory Board may be dismissed at any time during their term of office by a resolution of the shareholders' meeting adopted by at least a simple majority of the votes cast. In addition, any member of our Supervisory Board may resign at any time by giving one month's written notice – or, in the event of cause, giving written notice with immediate effect – of his or her resignation to the Management Board.

Our Supervisory Board elects a chairperson and a deputy chairperson from its members. The deputy chairperson exercises the chairperson's rights and obligations whenever the chairperson is unable to do so. The members of our Supervisory Board have elected Helmut Jeggle as chairperson and Ulrich Wandschneider as deputy chairperson, each for the term of their respective membership on our Supervisory Board.

The Supervisory Board meets at least twice each calendar half-year. Our Articles of Association provide that a quorum of the Supervisory Board members is present if at least three of its members participate in the vote. Members of our Supervisory Board are deemed present if they attend the meeting via telephone or other (electronic) means of communication (including via video conference) or submit their written vote through another member. Additionally, our Articles of Association allow for resolutions to be taken via telephone or other (electronic) means of communications (including via video conference).

Resolutions of our Supervisory Board are passed by the vote of a simple majority of the votes cast unless otherwise required by law, our Articles of Association or the rules of procedure of our Supervisory Board. In the event of a tie, the chairperson of the Supervisory Board has the casting vote. Our Supervisory Board is not permitted to make management decisions, but in accordance with European and German law and in addition to its statutory responsibilities, it has determined that certain matters require its prior consent, including:

- entering into certain large transactions;
- creating or holding any interest in businesses (except wholly owned subsidiaries) or disposing of shares in businesses (except for a sale of JPT);
- issuing shares from authorized capital, unless the shares are issued pursuant to a redemption of stock appreciation rights; and
- acquiring treasury shares in return for valuable consideration.

Each member of the Supervisory Board shall disclose any conflicts of interest to the Supervisory Board, especially those that may arise from providing advice or holding any offices or board positions at customers, suppliers, creditors or other third parties. Material conflicts of interest that are not merely temporary and that are specific to a particular Supervisory Board member shall result in this particular member leaving office. Our Supervisory Board also puts in place adequate measures to limit, prevent or resolve conflicts of interest in accordance with applicable legal requirements and the Company's Conflicts of Interest Policy.

Our Supervisory Board conducted a self-assessment for the year ended December 31, 2023. It covered all key aspects of the Supervisory Board's work, including its committees, its composition, its competence profile, its main topics and its relationship with the Management Board. The results of the self-assessment have been evaluated and will subsequently be presented to the Supervisory Board. Based on the self-assessment, the Supervisory Board believes that it, its committees and the Management Board continue to operate at a professional and cooperative level. No fundamental need for change was identified.

Supervisory Board Practices

Decisions are generally made by our Supervisory Board as a whole, however decisions on certain matters may be delegated to committees of our Supervisory Board to the extent permitted by law. The chairperson, or if he or she is prevented from doing so, the deputy chairperson, chairs the meetings of the Supervisory Board and determines the order in which the agenda items are discussed, the method and order of voting, as well as any adjournment of the discussion and

passing of resolutions on individual agenda items after a due assessment of the circumstances. Our Supervisory Board may designate further types of actions as requiring its approval.

In addition, each member of the Supervisory Board is obliged to carry out his or her duties and responsibilities personally, and such duties and responsibilities cannot be generally and permanently delegated to third parties. However, the Supervisory Board and its committees have the right to appoint independent experts for the review and analysis of specific circumstances in accordance with its control and supervision duties under applicable European and German law. We would bear the costs of any such independent experts that are retained by the Supervisory Board or any of its committees.

Pursuant to Section 107 para. 3 of the German Stock Corporation Act (*Aktiengesetz*), the Supervisory Board may form committees from among its members and charge them with the performance of specific tasks. The committees' tasks, authorizations and processes are determined by the Supervisory Board. Where permissible by law, important powers of the Supervisory Board may also be transferred to committees.

The Supervisory Board has established an Audit Committee, a Compensation, Nominating, Governance Committee and a Capital Markets and Product Committee by resolution. The Product Committee was established as of October 1, 2023. Set forth in the table below are the members of the respective committees during the year ended December 31, 2023.

Name of Committee	Members
Audit Committee	Prof. Anja Morawietz, Ph.D. (Chair), Prof. Rudolf Staudigl, Ph.D and Ulrich Wandschneider, Ph.D.
Compensation, Nominating and Corporate Governance Committee	Prof. Rudolf Staudigl, Ph.D. (Chair), Baroness Nicola Blackwood (since May 25, 2023), Prof. Christoph Huber, M.D (until May 25, 2023) and Michael Motschmann.
Capital Markets Committee	Helmut Jeggler (Chair), Prof. Anja Morawietz, Ph.D. and Michael Motschmann
Product Committee (est. October 1, 2023)	Ulrich Wandschneider, Ph.D. (Chair), Baroness Nicola Blackwood and Helmut Jeggler

Audit Committee

Our Audit Committee for the year ended December 31, 2023 consisted of Anja Morawietz. (Chair), Rudolf Staudigl and Ulrich Wandschneider. The Audit Committee assists the Supervisory Board in overseeing the accuracy and integrity of our financial statements, our accounting and financial reporting processes and audits of our financial statements, the effective functioning of our internal control system, our risk management system, our compliance with legal and regulatory requirements, our independent auditor's qualifications and independence, the performance of the independent auditor and the effective functioning of our internal audit functions, and, subject to certain limitations, adopts and implements pertinent decisions on behalf of the Supervisory Board. The Audit Committee's duties and responsibilities to carry out its purpose, include, among others:

- making a recommendation to the Supervisory Board with respect to the proposal for the appointment of the auditors;
- considering the commissioning of the audit engagement, as well as the compensation, retention and oversight of the independent auditor;
- evaluating the qualifications, independence and quality of performance of the independent auditor;
- reviewing and pre-approving the audit and non-audit services to be performed by the independent auditor;
- reviewing and discussing with the independent auditor and management the annual audit plan, as well as critical accounting policies and practices to be used;
- discussing and determining additional areas of audit focus, as appropriate;
- reviewing and discussing with the independent auditor and management the adequacy and effectiveness of our internal accounting controls and critical accounting policies;
- reviewing and discussing with the independent auditor and management the results of our annual audit;

- reviewing non-financial reporting;
- reviewing the effectiveness of the compliance management system;
- reviewing and discussing with the independent auditor and management any quarterly or annual earnings announcements;
- reviewing any related party transactions and reviewing and monitoring potential conflict of interest situations on an ongoing basis for compliance with our policies and procedures; and
- overseeing procedures for the receipt, retention and treatment of complaints received regarding accounting, internal accounting controls or auditing matters.

Within the limits of applicable European and German law, the Audit Committee shall have the resources and authority appropriate to discharge its duties and responsibilities, including the authority to select, retain, terminate, and approve the fees and other engagement terms of special or independent counsel, accountants or other experts and advisors, as it deems necessary or appropriate for so discharging its duties and responsibilities, without seeking approval of the Management Board or Supervisory Board.

All members of the Audit Committee qualify as “independent directors” as such term is defined in Rule 10A-3 under the Exchange Act and Nasdaq Rule 5605. Additionally, our Supervisory Board has determined that each of Anja Morawietz, Rudolf Staudigl and Ulrich Wandschneider qualifies as “audit committee financial expert” as that term is defined under the Exchange Act. In addition, Anja Morawietz as Chair of the Audit Committee, Rudolf Staudigl and Ulrich Wandschneider have the special knowledge and experience required by the German Corporate Governance Code in the field of accounting and expertise in the field of auditing.

Compensation, Nominating and Corporate Governance Committee

Our Compensation, Nominating and Corporate Governance Committee for the year ended December 31, 2023 consisted of Rudolf Staudigl (Chair), Nicola Blackwood (since May 25, 2023), Christoph Huber (until May 25, 2023) and Michael Motschmann. The Compensation, Nominating and Corporate Governance Committee’s duties and responsibilities to carry out its purpose include, among others:

- preparing and discussing with management policies relating to the remuneration of the members of our Management Board;
- reviewing and supervising corporate goals and objectives for the remuneration of the members of the Management Board, including evaluation of the performance of the members of the Management Board in light of these goals and proposals to the Supervisory Board for remuneration based on such evaluations;
- reviewing all equity-based compensation plans and arrangements and making recommendations to the Supervisory Board regarding such plans;
- assisting with identifying and recruiting candidates to fill positions on the Management Board and the Supervisory Board;
- considering any corporate governance issue that arises and developing appropriate recommendations for the Supervisory Board; and
- overseeing the evaluation of the Supervisory Board and reporting on its performance and effectiveness.

Capital Markets Committee

Our Capital Markets Committee for the year ended December 31, 2023 consisted of Helmut Jeggle (Chair), Anja Morawietz and Michael Motschmann. The Capital Markets Committee advises and makes recommendations to the Supervisory Board on issues in connection with capital measures and takeover, merger and acquisition activities. Its responsibilities include the following tasks:

- overseeing the activities of the Company relating to its capital structure and capital raising, including preparation for and implementation of public offerings and share issuances; and
- overseeing the activities of the Company relating to takeovers, mergers and acquisitions activities.

Product Committee

Following the discussions in the Supervisory Board and related workshops with members of the Management Board during 2023, our Product Committee was established as of October 1, 2023 and consists of Ulrich Wandschneider (Chair), Nicola Blackwood and Helmut Jeggle. The Product Committee advises and makes recommendations to the Supervisory Board with respect to our strategy and investment in research and development programs and product launch preparations including commercialization. Its responsibilities include the following tasks:

- advising on strategy, execution and communication regarding relevant go-to-market efforts;
- overseeing the activities relating to a) product development, b) launch plans and c) it's execution; and
- advising on market potential for products in clinical development.

Management Board

Our Supervisory Board determines the exact number of members of our Management Board, which must consist of at least two members. Pursuant to the Articles, the Supervisory Board may also appoint a chairperson or a spokesman of the Management Board. Ugur Sahin has been appointed the chair of the Management Board.

The members of our Management Board are appointed by our Supervisory Board for a term of up to five years. They are eligible for reappointment or extension, including repeated re-appointment and extension, after the completion of their term in office, in each case again for up to an additional five years. Under certain circumstances, such as a serious breach of duty or a vote of no confidence by the shareholders in a shareholders' meeting, a member of the Management Board may be removed from office by our Supervisory Board prior to the expiration of his or her term.

The members of our Management Board conduct the daily business of the Company in accordance with applicable laws, our Articles of Association and the rules of procedure for the Management Board adopted by our Supervisory Board. They are generally responsible for the management of our company and for handling our daily business relations with third parties, the internal organization of our business and communications with our shareholders.

A member of the management board of an SE governed by German law may not deal with or vote on matters relating to proposals, arrangements or contractual agreements between himself or herself and the Company, and a member of our Management Board may be liable to us if he or she has a material interest in any contractual agreement between the Company and a third party which is not disclosed to and approved by our Supervisory Board.

The rules of procedure for our Management Board provide that certain matters require a resolution of the entire Management Board, in addition to transactions for which a resolution adopted by the entire Management Board is required by law or required by our Articles of Association. In particular, the entire Management Board shall decide on, among others:

- the budget plan for the following year, which is to be presented by the Management Board to the Supervisory Board by December 10 of each year;
- presentation of the Company's financial statements and consolidated financial statements and reviews of operations of the Company and the Group;
- reporting to the Supervisory Board;
- all measures and transactions that require the Supervisory Board's approval;
- all measures and transactions that are of fundamental importance or involve an extraordinary economic risk to us, including without limitation, establishing new lines of business or discontinuing existing ones, acquisitions or sales of material business assets, material interests, holdings and investments and material contracts or transactions;
- convening the Company's shareholders' meetings and proposals for resolutions by the Company's shareholders' general meetings; and
- appointment and termination of key managers in the Group.

Code of Conduct and Conflicts of Interest Policy

We have adopted a Code of Business Conduct & Ethics, or Code of Conduct, which outlines the principles of legal and ethical business conduct under which we do business. The Code of Conduct applies to all of our Supervisory Board members, Management Board members, directors of our subsidiaries and employees. The full text of the Code of Conduct is available on our website at <https://www.biontech.de>. The information and other content appearing on our website are not incorporated by reference into this Annual Report and our website address is included in this report as an inactive textual reference only. Any amendments or waivers from the provisions of the Code of Conduct for members of our Supervisory or Management Boards will be made only after approval by our Supervisory Board and will be disclosed on our website promptly following the date of such amendment or waiver.

We have also adopted a Conflicts of Interest Policy which sets forth the procedures by which we manage potential and actual conflicts of interest. Under the Conflicts of Interest Policy, which applies to all of our Supervisory Board members, Management Board members, directors of our subsidiaries and employees, an actual, potential or perceived conflict of interest must be disclosed when it first arises. If the conflict is transactional in nature and involves a member of the Management Board or the Supervisory Board, the Management or Supervisory Board, as the case may be, with the abstention of the conflicted member, shall decide whether to approve the transaction.

In addition, we have implemented compliance policies that describe the compliance management systems that have been implemented for us and our subsidiaries. Our compliance policies are designed to ensure compliance with applicable legal requirements, while at the same time implementing high ethical standards that are mandatory for both management and each employee. The overall responsibility for the compliance management system lies with the Management Board. The Audit Committee will receive regular reports on the operation of the compliance management system.

D. Employees

As of December 31, 2023, we had 6,133 full-time equivalent employees working for us, of whom 1,168 hold a doctoral degree or higher. The following tables provides an overview of employee full-time equivalent broken down by function and by the regions European, North America, Asia and Africa.

Full-time equivalents	Clinical Research & Development	Scientific Research & Development	Operations	Quality	Supporting Functions	Commercial & Business Development	Σ
Europe	486	1,555	1,440	450	1,184	185	5,299
North America	90	440	7	7	109	7	660
Asia	—	—	24	—	4	—	28
Africa	—	19	59	—	68	—	146
Total as of December 31, 2023	576	2,014	1,530	457	1,365	192	6,133
Europe	243	1,102	1,300	384	924	140	4,093
North America	—	356	—	—	76	—	432
Asia	2	—	—	—	3	—	5
Total as of December 31, 2022	245	1,458	1,300	384	1,003	140	4,530
Europe	143	812	1,015	290	503	83	2,846
North America	—	188	—	—	46	—	234
Asia	—	—	—	—	2	—	2
Total as of December 31, 2021	143	1,000	1,015	290	551	83	3,082

None of our employees has engaged in any labor strikes. We apply the collective labor agreements of the chemical industry and related industries at our Marburg site. We have works councils at our Idar-Oberstein, Mainz, Marburg, Munich and Berlin (JPT Peptide Technologies GmbH) sites as well as a group works council (*Konzernbetriebsrat*). Further, we maintain a couple of works agreements (*Betriebsvereinbarungen*) and group works agreements

(Konzernbetriebsvereinbarungen) with respect to certain topics at our Idar-Oberstein, Mainz, Marburg and Berlin (JPT Peptide Technologies GmbH) sites or the group. We consider our relationship with our employees to be positive and have not experienced any major labor disputes.

E. Share Ownership

The share ownership information with respect to Management Board and Supervisory Board members is presented in Item 7 below.

F. Disclosure of a Registrant's Action to Recover Erroneously Awarded Compensation

Not applicable.

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table presents information, as of December 31, 2023 regarding the beneficial ownership of our ordinary shares for:

- each person, or group of affiliated persons, known by us to own beneficially 5% or more of our outstanding shares;
- each member of our Supervisory Board;
- each member of our Management Board; and
- all members of our Supervisory Board and Management Board as a group.

The number of ordinary shares beneficially owned by each entity, person, and member of our Supervisory Board and our Management Board is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any ordinary shares over which the individual has sole or shared voting power or investment power as well as any ordinary shares that the individual has the right to acquire within 60 days of December 31, 2023 through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all ordinary shares held by that person. All of our ordinary shares and ADSs representing our ordinary shares vote on an equal basis.

The percentage of outstanding ordinary shares is computed on the basis of 237,725,735 ordinary shares outstanding as of December 31, 2023. This amount excludes 10,826,465 shares held in treasury. Amounts presented in this section include ordinary shares held in the form of ADSs. Unless otherwise indicated, the address for each beneficial owner is An der Goldgrube 12, 55131 Mainz, Germany.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage Beneficially Owned
5% shareholders		
AT Impf GmbH ⁽¹⁾	104,049,145	43.8 %
Medine GmbH ⁽²⁾	40,439,542	17.0 %
All 5% shareholders, as a group	144,488,687	60.8 %
Members of the Supervisory Board and the Management Board		
Prof. Ugur Sahin, M.D. ⁽³⁾	41,295,728	17.4 %
Jens Holstein	1,620	(9)
Sean Marett ⁽⁴⁾	815,263	(9)
Sierk Poetting, Ph.D. ⁽⁵⁾	754,784	(9)
Ryan Richardson	14,695	(9)
James Ryan, Ph.D.	—	—
Prof. Özlem Türeci, M.D.	913,247	(9)
Helmut Jeggle ⁽⁶⁾	1,525,967	(9)
Ulrich Wandschneider, Ph.D. ⁽⁷⁾	1,480	(9)
Baroness Nicola Blackwood	—	—
Prof. Anja Morawietz, Ph.D. ⁽⁸⁾	240	(9)
Michael Motschmann	—	—
Prof. Rudolf Staudigl, Ph.D.	400	(9)
All members of our Supervisory Board and Management Board, as a group	45,323,424	19.1 %

⁽¹⁾ Information herein is based upon a Schedule 13G/A jointly filed with the SEC on February 7, 2024 by ATHOS KG, AT Impf GmbH and Thomas Maier. Consists of 104,049,145 ordinary shares held by AT Impf GmbH. The sole member of AT Impf GmbH is ATHOS KG, and, as a result, ATHOS KG is deemed to be the beneficial owner of the securities held by AT Impf GmbH. ATHOS KG via AT Impf GmbH has de facto control over BioNTech based on its substantial shareholding, which practically enables it to exercise the majority of voting rights to pass resolutions at our Annual General Meeting, or AGM. As of December 31, 2023 Thomas Maier is a general partner (Komplementär) of ATHOS KG and may be deemed to be beneficial owners of the securities held by AT Impf KG. Mr. Maier disclaims beneficial ownership of such shares except to the extent of their pecuniary interest therein.

⁽²⁾ Information herein is based upon a Schedule 13G/A jointly filed with the SEC on February 14, 2024 by Medine GmbH and Ugur Sahin. The sole shareholder of Medine GmbH is Ugur Sahin, and, as a result, Ugur Sahin is deemed to be the beneficial owner of the securities held by Medine GmbH. Consists of 40,439,542 ordinary shares held by Medine GmbH, 1,328,152 of which are held for the benefit of a former colleague pursuant to a trust arrangement. Pursuant to this arrangement, Medine GmbH retains voting power, but not dispositive power, over such shares for so long as such shares are held in trust and accordingly Medine GmbH and Ugur Sahin each may be deemed beneficially to own such shares.

⁽³⁾ Consists of the shares described in note 2 above, plus 856,186 ordinary shares held directly by Ugur Sahin. He is the sole shareholder of Medine GmbH.

⁽⁴⁾ Consists of (a) 705,936 ordinary shares held by RLG GmbH (Sean Marett is the sole shareholder of RLG GmbH), (b) 109,327 ordinary shares held directly by Sean Marett.

⁽⁵⁾ Consists of (a) 606,025 ordinary shares held by Tofino GmbH (Sierk Poetting is sole shareholder of Tofino GmbH), (b) 148,759 ordinary shares held directly by Sierk Poetting and (c) 1,638 ordinary shares held by immediate family members of Mr. Poetting. Mr. Poetting disclaims beneficial ownership of the 1,638 ordinary shares held by immediate family members except to the extent of his pecuniary interest therein.

⁽⁶⁾ Consists of (a) 332,316 ordinary shares held directly by Helmut Jeggle and (b) 1,193,651 ordinary shares held by Salvia GmbH.

⁽⁷⁾ Consists of 1,480 ordinary shares held by beebusy Capital GmbH. Ulrich Wandschneider is sole shareholder of beebusy Capital GmbH.

⁽⁸⁾ Consists of (a) 200 ordinary shares held directly by Anja Morawietz and (b) 40 ordinary shares held by immediate family members of Anja Morawietz.

⁽⁹⁾ Less than one percent.

Holdings by U.S. Shareholders

Our share capital consists of ordinary shares, some of which are traded in the United States by means of American Depositary Shares (ADSs), each representing one ordinary share. Our depository, The Bank of New York Mellon, is the holder of the ordinary shares underlying the ADSs. Based on the limited information available to us and the depository, we generally cannot determine with certainty the number of U.S. shareholders or how many shares such shareholders own.

B. Related Party Transactions

See Item 18.

C. Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

A. Consolidated Statements and Other Financial Information

See Item 18.

B. Significant Changes

Not applicable.

Item 9. The Offer and Listing

A. Offer and Listing Details

ADSs representing our ordinary shares have been listed on the Nasdaq Global Select Market under the symbol “BNTX” since October 10, 2019. Prior to that date, there was no public trading market for our ADSs.

B. Plan of Distribution

Not applicable.

C. Markets

ADSs representing our ordinary shares have been listed on the Nasdaq Global Select Market under the symbol “BNTX” since October 10, 2019.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

General

We were incorporated as a German stock corporation (*Aktiengesellschaft*) with the legal name Petersberg 91. V AG under the laws of the Federal Republic of Germany on June 2, 2008. We changed our name to BioNTech AG on December 11, 2008. Effective as of March 8, 2019, the date on which the change of legal form and company was registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) of Mainz, Germany, we converted to a *Societas Europaea* with the legal name BioNTech SE. We completed our initial public offering in October 2019. The principal legislation under which we operate and our shares are issued are the Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE), the German Law on the Implementation of Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE) (*Gesetz zur Ausführung der Verordnung (EG) NR. 2157/2001 des Rates vom 8. Oktober 2001 über das Statut der Europäischen Gesellschaft (SE) (SE-Ausführungsgesetz—SEAG)*) and the German Stock Corporation Act (*Aktiengesetz*), in each case as amended.

We are registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) in Mainz, Germany, under number HRB 48720. Our statutory seat is in Mainz, Germany, and our registered office is An der Goldgrube 12, 55131 Mainz, Germany. Copies of our Articles of Association (*Satzung*) are publicly available from the commercial register (*Handelsregister*) at the local court of Mainz, Germany, electronically at www.unternehmensregister.de and as an exhibit to this Annual Report.

Share Capital

We have share capital registered in the commercial register (*Handelsregister*) in the amount of €248,552,200, which is divided into 248,552,200 registered shares (*Namensaktien*). All shares are shares with no par value (*Stückaktien ohne Nennbetrag*) with a notional amount attributable to each ordinary share of €1.00. Each issued ordinary share is fully paid.

Form, Certification and Transferability of Shares

The form and contents of our share certificates, collective share certificates and global share certificates are determined by our Management Board. A shareholder's right to certification of its shares is excluded, to the extent permitted by law and to the extent that certification is not required by the stock exchange on which the shares or rights or certificates representing them are admitted to trading. We are permitted to issue collective share certificates and global share certificates that represent multiple or all of our shares.

Our shares are freely transferable under German law.

Changes in Our Share Capital During the Last Three Financial Years

Our share capital as registered with the commercial register (*Handelsregister*) amounts to €248,552,200, including an amount of €10,826,465 relating to 10,826,465 ordinary shares held in treasury as of December 31, 2023. Since January 1, 2021, our share capital has changed as follows:

- On March 24, 2022, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 497,727 shares; and
- On May 20, 2022, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 1,744,392 shares.

Anti-takeover Provisions of Our Charter Documents

Our Articles of Association (*Satzung*) do not include any provisions that would have a direct effect of delaying, deferring or preventing a change of control. However, in the event of a hostile takeover, we could use our authorized capital to increase our share capital to issue new shares to an investor at a premium. An increase in the number of shares outstanding could have a negative effect on a party's ability to carry out a hostile takeover. The provisions of German law relating to public bids and takeovers that require any such bids to be carried out in a manner designed to safeguard equal and fair treatment to all shareholders and give them a right to be bought out at an adequate compensation where a party acquires "control" (as such term is defined in such provisions) over the relevant company do not apply.

Future Changes to the Share Capital

Authorized Capital

Under the relevant law, the general meeting of a European stock corporation (*Societas Europaea*) governed by German law can authorize the Management Board, with the consent of the Supervisory Board, to issue shares in a specified aggregate nominal amount of up to 50% of the issued share capital of such company at the time the resolution becomes effective. The shareholders' authorization becomes effective upon registration in the commercial register (*Handelsregister*) and may extend for a period of no more than five years thereafter. Under § 4(5) of our Articles of Association (*Satzung*), the Management Board is authorized to increase our share capital, on one or more occasions, by a total of up to €122,657,313 by issuing, on one or more occasions, up to 122,657,313 new, registered shares with no par value (*Genehmigtes Kapital*), in each case with consent of the Supervisory Board. This authorization expires on June 21, 2026.

Any new shares issued from the authorized capital will participate in the profits starting with the financial year for which the annual financial statements have not yet been submitted to the general meeting at the time of registration of the implementation of the capital increase. Further details of a capital increase from the authorized capital may be specified by the Management Board.

Conditional Capital

Pursuant to § 4(6) of our Articles of Association (*Satzung*), our share capital is conditionally increased by €16,212,917 through issuance of new, registered shares with no par value (*Bedingtes Kapital ESOP 2017/2019*). The conditional capital may only be used to issue shares to the holders of option rights granted under our ESOP to members of our Management Board and to certain of our employees.

The conditional capital increase will only be implemented to the extent that stock options under our ESOP are exercised and such stock options are not serviced by our providing treasury shares or through cash payments. Any new shares issued under the conditional capital pursuant to § 4(6) of our Articles of Association (*Satzung*) shall be entitled to dividends from the beginning of the previous financial year in case they are created by the exercise of subscription rights until the start of the Annual General Meeting of the Company and otherwise from the beginning of the financial year in which they are created as a result of the exercise of the stock options.

Pursuant to § 4(7) of our Articles of Association (*Satzung*), our share capital is conditionally increased by €85,754,868 through issuance of new, registered shares with no par value (*Bedingtes Kapital WSV 2019*). The conditional capital may only be used to issue shares to the holders or creditors of option rights or conversion rights or those under an obligation to convert under warrant-linked or convertible bonds avail of their option rights or conversion rights or where they are under an obligation to convert, to the extent they satisfy their obligation to convert, or to the extent that we exercise a right to choose to grant our shares, in whole or in part instead of paying a monetary amount due, and to the extent cash compensation is not granted in each relevant case or treasury shares or shares of another stock-listed company are not utilized for servicing.

Any new shares issued under the said conditional capital pursuant to the said § 4(7) of our Articles of Association shall carry an entitlement to dividends from the beginning of the financial year in which they are created; however, as far as the law permits, the Management Board can confer dividend rights for new shares in derogation of the foregoing.

Pursuant to § 4(8) of our Articles of Association (*Satzung*), our share capital is conditionally increased by €8,418,091 through issuance of new, registered shares with no par value (*Bedingtes Kapital ESOP 2021*). The conditional capital serves exclusively to grant rights to the holders of stock options issued by the Company in accordance with the authorization granted by the Annual General Meeting on June 22, 2021 under agenda item 6 letter d) (the "Authorization 2021").

The conditional capital increase will only be implemented to the extent that stock options under our ESOP are exercised by the holders of the stock options issued by the Company on the basis of Authorization 2021 and such stock options are not settled by the Company with treasury shares or through cash payments. Any new shares issued under the conditional capital pursuant to § 4(8) of our Articles of Association (*Satzung*) shall participate in profits from the beginning of the preceding financial year in case they are created by the exercise of subscription rights until the start of the annual general meeting of the Company and otherwise from the beginning of the financial year in which they are created as a result of the exercise of the stock options.

Preemptive Rights

German law generally provides shareholders with preemptive rights when new shares convertible bonds, bonds with warrants, profit participation rights or participating bonds are issued. This requirement, however, may also be satisfied by way of a credit institution subscribing for the securities and then offering them to the shareholders for purchase (*mittelbares Bezugsrecht*).

Further, it is possible for a shareholder resolution approved by three-quarters of the share capital voting on the resolution to exclude preemptive rights both where the general meeting itself resolves that the new securities are to be issued and in relation to the authorized capital, *i.e.*, an authorization for the Management Board, with the consent of the Supervisory Board, to resolve on the issuance of new securities; provided, however, that in each case, the exclusion or the authorization to exclude preemptive rights, respectively, must be justified by specific facts, in accordance with established case law of the German Federal Court of Justice (*BGH*). The German Federal Court of Justice (*BGH*) considers the exclusion of subscription rights justified if it (i) serves a purpose in the company's interests, (ii) is suitable for attaining such purpose, and (iii) is necessary and appropriate. Additionally, the Management Board must submit a written report to the shareholders' meeting in which it presents the reasons for the exclusion of the subscription rights.

Accordingly, under our Articles of Association (*Satzung*), the Management Board may, with the consent of the Supervisory Board, exclude such preemptive rights in a capital increase from the authorized capital in the following circumstances:

- to exclude fractional amounts from the subscription right;
- in the case of a capital increase against cash contributions, if the issue price of the new shares is not significantly lower than the market price of the company's shares already listed on the stock exchange at the time the issue price is finally determined. However, this authorization shall only apply subject to the provision that the shares issued excluding subscription rights in accordance with Section 186(3) Sentence 4 AktG may not exceed a total of 10% of the share capital either at the time this authorization takes effect or, if this amount is lower, at the time this authorization is exercised. This limit of 10% of the share capital includes shares which are issued or disposed of during the term of this authorization until the date of its exercise in direct or equivalent application of Section 186(3) Sentence 4 AktG. Shares which are used to service bonds with convertible or option rights or convertible obligations are to be offset against the 10% limit if these bonds were issued under exclusion of shareholder subscription rights in accordance with Section 186(3) Sentence 4 AktG during the entitlement period. Treasury shares are to be offset against the 10% limit, where they were disposed of by the company during the term of this authorization with the exclusion of subscription rights pursuant to or in analogous application of Section 186(3) Sentence 4 AktG;
- in the case of capital increases in exchange for contributions in kind, in particular in order to be able to offer the shares to third parties when purchasing companies, parts of companies or interests in companies as well as licenses or industrial property rights;
- in order to grant subscription rights to new shares to holders of conversion or option rights in respect of bonds issued by the company or its subordinated domestic or foreign Group companies, to the extent to which they would be entitled after exercising their conversion or option rights or after fulfilling an agreed conversion obligation;
- to implement an election dividend by which shareholders are given the option to contribute their dividend entitlements (either in whole or part) as a contribution in kind against issuance of our new shares;
- in capital increases, in each case if excluding subscription rights, according to the assessment by the Management Board, is expedient to the shares' successful placement in view of the requirements of eligible investors and if the discount by which the issue price of the shares may be below the current stock exchange price at the time the Management Board adopts the resolution on using authorized capital, according to the assessment by the Management Board, does not exceed the extent necessary for a successful placement and in any case does not exceed 10% of either the latest available closing price at the time when the issue price is fixed or the volume-weighted average price over a period of up to five trading days ending on the day on which the issue price is so fixed;
- in case shares are to be issued to a member of our Management Board or to another person who is employed by us or one of our affiliates and a minimum holding period of at least one year and the obligation to transfer back

the shares in the event that the beneficiary is not employed by us or one of our affiliated companies for the entire duration of the holding period or any other agreed period is agreed upon. Additional restrictions with regard to the shares issued may be agreed upon; and

- in order to be able to satisfy an option to acquire additional ordinary shares or American Depositary Shares that has been agreed with the issuing banks in connection with a public offering of our shares in the form of American Depositary Shares.

The total number of new shares issued from the authorized capital and under exclusion of subscription rights pursuant to bullets one through three and six above may not exceed 20% of the share capital, either at the time that the amendment to the Articles of Association (*Satzung*), resolved upon by the general meeting of June 26, 2020, came into effect or, if lower, at the time of utilization of the authorization. To be counted against the aforementioned 20% limit are: (i) those shares issued or to be issued to service conversion or option rights or conversion or option obligations or tender rights of the issuer under bonds, if the bonds have been issued during the term of this authorization up to the time of its exercise, excluding the subscription rights of shareholders, as well as, to a certain extent (ii) treasury shares that have been disposed under exclusion of subscription rights during the term of this authorization (except in the case of certain exceptions of the resolution to item no. 8 of the general meeting of August 19, 2019).

Corporate Purpose of our Company

Our business objective, as described in § 2 of our Articles of Association (*Satzung*), is to research and develop, as well as the manufacture and marketing of immunological and RNA-based drugs and test methods for the diagnosis, prevention and treatment of cancer, infectious diseases and other serious diseases.

Shareholders' Meetings and Voting Rights

Pursuant to our Articles of Association (*Satzung*), shareholders' meetings may be held in person or virtually at our seat or in any municipality in Germany with more than 500,000 inhabitants. Generally, shareholders' meetings are convened by our Management Board, or our Supervisory Board. Shareholders representing in the aggregate at least five percent of our ordinary shares may, subject to certain formal prerequisites, request that a shareholders' meeting be convened. Shareholders representing in the aggregate at least five percent of our ordinary shares or owning shares with an aggregate nominal value of at least €500,000 may request the addition of one or several items to the agenda of any shareholders' meeting. Shareholders' meetings may be summoned either via publication in the German Federal Gazette (*Bundesanzeiger*) or via mail or email, in each case generally at least 30 days before the meeting.

Shareholders may participate and vote in the shareholders' meeting if they are registered as a shareholder with the Company's share register. A shareholder who wishes to attend the shareholders' meeting—either in person or by proxy, which may also be appointed by us (*Stimmrechtsvertreter*)—must register for the meeting, which registration must occur no later than six days before the meeting (or at a later date, if so determined by our Management Board).

Each share carries one vote at a shareholders' meeting. Resolutions are, in accordance with our Articles of Association (*Satzung*), generally taken by simple majority of the votes cast. However, under applicable German and European law, a number of resolutions must be passed by either a three-quarter majority of the votes cast or a three-quarter majority of the share capital represented at the meeting. The fact that in these cases the quorum is determined in relation to the share capital or shares present (as opposed to, for example, all shares eligible to vote) means that holders of a minority of our shares could potentially control the outcome of resolutions.

Claims against Directors and Shareholders' Derivative Actions

Under German law, generally, the company, rather than its shareholders, is the proper claimant in an action with respect to a wrong committed against the company, or in cases where there is an irregularity in the company's internal management or supervision. Therefore, such claims may only be raised by the company represented by its management board, or, in the case of a wrong committed by a member of the Management Board, by the Supervisory Board. This concerns, in particular, claims against members of the Management Board or the Supervisory Board.

However, pursuant to German case law, the Supervisory Board is obliged to pursue the company's claims against the Management Board, unless the interest of the company keeps them from doing so. Further, the Management Board, or, if a claim is against a member of the Management Board, the Supervisory Board, is obliged to pursue the company's claims

against the designated individuals if so resolved by a simple majority of votes cast during a shareholders' meeting. With a simple majority of votes, shareholders can also request that a representative pursue the claim on behalf of the company. The court may appoint such a representative upon the request of shareholders holding at least 10% of the company's share capital or a participation of at least €1,000,000 in the share capital.

If the company is unable to fulfill its third-party obligations, the company's creditors may pursue the company's damage claims against members of the Management Board for certain wrongdoings.

Under certain circumstances, shareholders can bring forward damage claims of the company against its management on their own behalf. In order to bring forward such a claim one shareholder alone or together with other shareholders needs to hold at least 1% of the company's share capital or a participation of €100,000 in the share capital. Additionally, the claimant(s) must comply with special claim approval procedures conducted before a competent court which will allow the pertinent request only if there are circumstances justifying the assumption that damage has been afflicted on the company by improper conduct or a gross breach of the law or the articles of association.

Dividend Rights

Under German law, distributions of dividends on shares for a given financial year are generally determined by a process in which the management board and supervisory board submit a proposal to the company's annual general shareholders' meeting held in the subsequent financial year and such annual general shareholders' meeting adopts a resolution.

German law provides that a resolution concerning dividends and distribution thereof may be adopted only if the company's unconsolidated financial statements prepared in accordance with German law show net retained profits. In determining the profit available for distribution, the result for the relevant year must be adjusted for profits and losses brought forward from the previous year and for withdrawals from or transfers to reserves. Certain reserves are required by law and must be deducted when calculating the profit available for distribution.

Shareholders generally participate in profit distributions in proportion to the number of shares they hold. Dividends on shares resolved by the general shareholders' meeting are paid annually, shortly after the general shareholders' meeting, in compliance with the rules of the respective clearing system. Dividend payment claims are subject to a three-year statute of limitation in the company's favor.

Authorization to Purchase and Sell Our Own Shares

We may not purchase our own shares unless authorized by the shareholders' meeting or in other very limited circumstances as set out in the German Stock Corporation Act. The Company's shareholders' meeting held on August 19, 2019 authorized the Management Board until August 18, 2024, provided it complies with the legal requirement of equal treatment, to acquire treasury shares up to a total of 10% of the Company's share capital at the time of the relevant resolution or at the time the authorization is exercised. These shares held by the Company (including shares attributable to it pursuant to the AktG) must never exceed 10% of the share capital. The shares may be purchased (i) through the stock exchange, (ii) by means of a public offer directed to all shareholders of the Company, (iii) by means of a public invitation to the shareholders to make a sales offer or (iv) from the Bill & Melinda Gates Foundation under very limited circumstances as specified in the authorization. Such shares may not be purchased for trading purposes. The Management Board is authorized to use the shares only as specified in the authorization.

Squeeze-Out of Minority Shareholders

Under German law, the shareholders' meeting of a stock corporation may resolve, upon request of a shareholder that holds at least 95% of the share capital, that the shares held by any remaining minority shareholders be transferred to the majority shareholder against payment of "adequate cash compensation" (*Ausschluss von Minderheitsaktionären*). This amount must take into account the full value of the company at the time of the resolution, which is generally determined using the future earnings value method (*Ertragswertmethode*).

A squeeze-out in the context of a merger (*umwandlungsrechtlicher Squeeze-Out*) only requires a majority shareholder to hold at least 90% of the share capital.

Liquidation Rights

Apart from liquidation, e.g., as a result of insolvency proceedings, we may be liquidated with a vote of the holders of at least three-quarters of the share capital represented at the shareholders' meeting at which such a vote is taken. If we are liquidated, any assets remaining after all of our liabilities have been paid off would be distributed among our shareholders in proportion to their holdings in accordance with German statutory law. The German Stock Corporation Act provides certain protections for creditors, which must be observed in the event of liquidation.

C. Material Contracts

Except as otherwise disclosed in this Annual Report (including the exhibits thereto), we are not currently, and have not been in the last two years, party to any material contract, other than contracts entered into in the ordinary course of our business.

D. Exchange Controls

There are currently no legal restrictions in the Federal Republic of Germany on international capital movements and foreign exchange transactions, except in limited embargo circumstances (*Teilembargo*) relating to certain areas, entities or persons as a result of applicable resolutions adopted by the United Nations and the European Union. Restrictions currently exist with respect to, among others, Armenia, Azerbaijan, Belarus, Bosnia, Burundi, D.R. Congo, Central African Republic, China, Guatemala, Guinea, Guinea-Bissau, Haiti, Iran, Iraq, Lebanon, Libya, Mali, Moldova and the Transnistria region, Myanmar, Nicaragua, Niger, North Korea, Russia, Somalia, South Sudan, Sudan, Syria, Tunisia, Türkiye, Ukraine, Venezuela, Yemen and Zimbabwe.

For statistical purposes, there are, however, limited notification requirements regarding transactions involving cross-border monetary transfers. With some exceptions, every corporation or individual residing in the Federal Republic of Germany must report to the German Central Bank (*Deutsche Bundesbank*) (i) any payment received from, or made to, a non-resident corporation or individual that exceeds €12,500 (or the equivalent in a foreign currency) and (ii) (with the exception of individuals residing in the Federal Republic of Germany) in case the sum of claims against, or liabilities payable to, non-resident corporations or individuals exceeds €5,000,000 (or the equivalent in a foreign currency) at the end of any calendar month. Payments include cash payments made by means of direct debit, checks and bills, remittances denominated in euros and other currencies made through financial institutions, as well as netting and clearing arrangements.

E. Taxation

German Taxation

The following discussion addresses certain German tax consequences of acquiring, owning or disposing of the ADSs. With the exception of “—Taxation of Holders Tax Resident in Germany” below, which provides an overview of dividend taxation and of capital gains taxation with respect to holders that are residents of Germany, this discussion applies only to U.S. treaty beneficiaries (defined below) that acquire the ADSs representing our ordinary shares.

This discussion is based on domestic German tax laws, including, but not limited to, circulars issued by German tax authorities, which, e.g., are not binding on the German courts, and the Treaty (defined below). It is based upon tax laws in effect at the time of filing of this report. These laws are subject to change, possibly with retroactive effect. For example, certain member states of the European Union are considering introducing a financial transaction tax (*Finanztransaktionssteuer*) which, if introduced, may also be applicable on sales and/or transfer of ADSs. In addition, in Germany, for example, there are currently ongoing discussions on an increase of the top tax rate, which may also have an effect on the German tax consequences of acquiring, owning and disposing of the ADSs. There is no assurance that German tax authorities will not challenge one or more of the tax consequences described in this section.

In addition, this discussion is based upon the assumption that each obligation in the deposit agreement and any related agreement will be performed in accordance with its terms. It does not purport to be a comprehensive or exhaustive description of all German tax considerations that may be of relevance in the context of acquiring, owning and disposing of ADSs.

The tax information presented in this report is not a substitute for tax advice. Prospective holders of ADSs should consult their own tax advisors regarding the German tax consequences of the purchase, ownership, disposition, donation or inheritance of ADSs in light of their particular circumstances, including the effect of any state, local, or other foreign or domestic laws or changes in tax law or interpretation. The same applies with respect to the rules governing the refund of any German dividend withholding tax (*Kapitalertragsteuer*) withheld. Only an individual tax consultation can appropriately account for the particular tax situation of each investor.

General

Based on the circular issued by the German Federal Ministry of Finance (*BMF-Schreiben*), dated May 24, 2013, reference number IV C 1-S2204/12/10003, as amended by the circular dated December 18, 2018 (reference number IV C 1 – S 2204/12/10003), in respect of the taxation of American Depositary Receipts, or ADRs, on domestic shares, or the ADR Tax Circular, for German tax purposes, the ADSs should, in light of the ADR Tax Circular, represent a beneficial ownership interest in the underlying shares of BioNTech and qualify as ADRs for the purpose of the ADR Tax Circular. If the ADSs qualify as ADRs under the ADR Tax Circular, dividends would accordingly be attributable to holders of the ADSs for German tax purposes, and not to the legal owner of the ordinary shares (*i.e.*, the financial institution on behalf of which the ordinary shares are stored at a domestic depository for the ADS holders). Furthermore, holders of the ADSs should be treated as beneficial owners of the capital of BioNTech with respect to capital gains (see below in section “—German Taxation of Capital Gains of the U.S. Treaty Beneficiaries of the ADSs”). However, investors should note that circulars published by the German tax authorities (including the ADR Tax Circular) are not, e.g., binding on German courts, including German tax courts, and it is unclear whether a German court would follow the ADR Tax Circular in determining the German tax treatment of the ADSs. For the purpose of this German tax section, it is assumed that the ADSs qualify as ADRs within the meaning of the ADR Tax Circular.

Taxation of Holders Not Tax Resident in Germany

The following discussion describes selected German tax consequences of acquiring the ADSs, owning the ADSs and disposing of the ADSs to a holder that is a U.S. treaty beneficiary. For purposes of this discussion, a “U.S. treaty beneficiary” is a resident of the United States for purposes of the Convention between the Federal Republic of Germany and United States of America for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income and Capital and Certain Other Taxes of 1989, as amended by the Protocol as of June 4, 2008 (*Abkommen zwischen der Bundesrepublik Deutschland und den Vereinigten Staaten von Amerika zur Vermeidung der Doppelbesteuerung und zur Verhinderung der Steuerverkürzung auf dem Gebiet der Steuern vom Einkommen und vom Vermögen und einiger anderer Steuern in der Fassung vom 4. Juni 2008*), hereinafter referred to as the “Treaty,” who is eligible for relevant benefits under the Treaty.

A holder will be a U.S. treaty beneficiary entitled to full Treaty benefits in respect of the ADSs if it is, inter alia:

- the beneficial owner of the ADSs (and the dividends paid with respect thereto);
- a U.S. tax resident corporation or individual;
- not also a resident of Germany for German tax purposes; and
- not subject to the limitation on benefits (*i.e.*, anti-treaty shopping) article of the Treaty that applies in limited circumstances.

Special rules apply to pension funds and certain other tax-exempt investors.

This discussion does not address the treatment of ADSs that are (i) held in connection with a permanent establishment or fixed base through which a U.S. treaty beneficiary carries on business or performs personal services in Germany or (ii) part of business assets for which a permanent representative in Germany has been appointed.

General Rules for the Taxation of Holders Not Tax Resident in Germany

Non-German resident holders of ADSs are subject to German taxation with respect to German source income (*beschränkte Steuerpflicht*). According to the ADR Tax Circular, income from the shares should be attributed to the holder of the ADSs for German tax purposes. As a consequence, income from the ADSs should be treated as German source income.

German Withholding Taxation of Dividends of the U.S. Treaty Beneficiaries of the ADSs

Generally, the full amount of a dividend distributed by BioNTech to a non-German resident holder, which does not maintain a permanent establishment or other taxable presence in Germany, is subject to (final) German withholding tax at an aggregate rate of 26.375% (that amount consists of 25% on dividends distributed plus solidarity surcharge of 5.5% on the amount of the withholding tax). The basis for the withholding tax is generally the dividend approved for distribution by our general shareholder's meeting. German withholding tax is withheld and remitted to the German tax authorities by (i) the disbursing agent (*i.e.*, the German credit institution, financial services institution, securities trading enterprise or securities trading bank (each as defined in the German Banking Act (*Kreditwesengesetz*) and in each case including a German branch of a foreign enterprise, but excluding a foreign branch of a German enterprise)) that holds or administers the underlying shares in custody and (a) disburses or credits the dividend income from the underlying shares, (b) disburses or credits the dividend income from the underlying shares on delivery of the dividend coupons or (c) disburses such dividend income to a foreign agent; or (ii) the central securities depository (*Wertpapiersammelbank*) in terms of the German Depository Act (*Depotgesetz*) holding the underlying shares in a collective deposit, if such central securities depository disburses the dividend income from the underlying shares to a foreign agent, regardless of whether a holder must report the dividend for tax purposes and regardless of whether or not a holder is a resident of Germany. Dividend payments, to the extent funded from BioNTech's tax-recognized contribution account (*steuerliches Einlagekonto*), subject to certain prerequisites, do not form part of the taxable dividend income but should lower the holder's acquisition costs for the ADSs.

Pursuant to the Treaty, the German withholding tax may generally not exceed (i) 15% of the gross amount of the dividends received by a U.S. treaty beneficiary other than a company holding ADSs which represent 10% or more of the voting shares in BioNTech, and (ii) 5% of the gross amount of the dividends received by a U.S. treaty beneficiary that is a company holding ADSs which represent 10% or more of the voting shares in BioNTech. The excess of the total withholding tax, including the solidarity surcharge, over the maximum rate of withholding tax permitted by the Treaty is refunded to U.S. treaty beneficiaries upon application. For example, for a declared dividend of 100, a U.S. treaty beneficiary initially receives 73.625 (100 minus the 26.375% withholding tax including solidarity surcharge). A U.S. treaty beneficiary other than a company holding ADSs which represent 10% or more of the voting shares in BioNTech is entitled to a partial refund from the German tax authorities in the amount of 11.375% of the gross dividend (of 100). As a result, the U.S. treaty beneficiary ultimately receives a total of 85 (85% of the declared dividend) following the refund of the excess withholding. However, it should be noted that there is uncertainty as to how the German tax authorities will apply the refund process to dividends on the ADSs with respect to non-German resident holders. Further, such refund is subject to the German anti-avoidance treaty shopping rule (as described below in "—Withholding Tax Refund for U.S. Treaty Beneficiaries").

German Withholding Taxation of Capital Gains of the U.S. Treaty Beneficiaries of the ADSs

The capital gains from the disposition of the ADSs realized by a non-German resident holder, which does not maintain a permanent establishment or other taxable presence in Germany, would be treated as German source income and be subject to German tax if the ADSs qualify as a Qualifying Participation. A Qualifying Participation exists if a holder at any time during the five years preceding the disposition, directly or indirectly, owned at least 1% of BioNTech's share capital, irrespective of whether through the ADSs or shares of BioNTech. If such holder had acquired the ADSs without consideration, the previous owner's holding period and quota would be taken into account.

Pursuant to the Treaty, capital gains from the disposal of a Qualifying Participation realized by a U.S. treaty beneficiary are, however, generally exempt from German taxation. Pursuant to the Treaty, U.S. treaty beneficiaries are not subject to German tax in relation to capital gains from the disposal of a Qualifying Participation even under the circumstances described in the preceding paragraph and therefore should not be subject to German taxation on capital gains from the disposition of the ADSs.

German statutory law requires the disbursing agent to levy withholding tax on capital gains from the sale of ADSs or other securities held in a custodial account in Germany. With regard to the German taxation of capital gains, disbursing agent means a German credit institution, financial services institution, securities trading enterprise or securities trading bank (each as defined in the German Banking Act and, in each case including a German branch if a foreign enterprise, but excluding a foreign branch of a German enterprise) that holds the ADSs in custody or administers the ADSs for the investor or conducts sales or other dispositions and disburses or credits the income from the ADSs to the holder of the ADSs. The German statutory law does not explicitly condition the obligation to withhold taxes on capital gains being subject to

taxation in Germany under German statutory law or on an applicable income tax treaty permitting Germany to tax such capital gains.

However, a circular issued by the German Federal Ministry of Finance, dated January 18, 2016, reference number IV C 1-S2252/08/10004 :017, as most recently amended by circular dated September 16, 2019, reference number IV C 1-S2252/08/10004 :027, provides that taxes need not be withheld when the holder of the custody account is not a resident of Germany for tax purposes and the income is not subject to German taxation. The circular further states that there is no obligation to withhold such tax even if the non-resident holder owns at least 1% of the share capital of a German corporation. While circulars issued by the German Federal Ministry of Finance are generally only to be adhered to by the German tax authorities but are, for example, not binding on the German courts, in practice, the disbursing agents nevertheless typically rely on guidance contained in such circulars. Therefore, a disbursing agent would only withhold tax at 26.375% on capital gains derived by a U.S. treaty beneficiary from the sale of ADSs held in a custodial account in Germany in the event that the disbursing agent did not follow the abovementioned guidance. In this case, the U.S. treaty beneficiary may be entitled to claim a refund of the withholding tax from the German tax authorities under the Treaty, as described below in “—Withholding Tax Refund for U.S. Treaty Beneficiaries.” A refund of taxes withheld on capital gains from the disposition of the ADSs which do not qualify as Qualifying Participations may also be claimed based on German statutory domestic law.

Withholding Tax Refund for U.S. Treaty Beneficiaries

U.S. treaty beneficiaries are generally eligible for treaty benefits under the Treaty, as described above in “—Taxation of Holders Not Tax Resident in Germany.” Accordingly, U.S. treaty beneficiaries are in general entitled to claim a refund of (i) the portion of the otherwise applicable 26.375% German withholding tax (*Kapitalertragsteuer*) on dividends that exceeds the applicable Treaty rate and (ii) the full amount of German withholding tax *Kapitalertragsteuer* on capital gains from the disposition of ADSs. The application for such claim is generally to be filed with the Federal Central Office of Taxation (*Bundeszentralamt für Steuern*) within four years after the end of the calendar year in which the capital gains or dividends have been received (*bezogen*).

However, in respect of dividends, the refund described in the preceding paragraph is only possible if, due to special rules on the restriction of withholding tax credit, the following three cumulative requirements are met: (i) the holder must qualify as beneficial owner of the ADSs for an uninterrupted minimum holding period of 45 days within a period starting 45 days prior to and ending 45 days after the due date of the dividends, (ii) the holder has to bear at least 70% of the change in value risk related to the ADSs during the minimum holding period as described under (i) of this paragraph and has not entered into (acting by itself or through a related party) hedging transactions which lower the change in value risk by more than 30%, and (iii) the holder must not be obliged to fully or largely compensate directly or indirectly the dividends to third parties. If these requirements are not met, then for a holder not being tax-resident in Germany who applied for a full or partial refund of the withholding tax pursuant to a double taxation treaty, no refund is available. This restriction generally does only apply if (a) the German tax underlying the refund application is below a tax rate of 15% based on the gross amount of the dividends and (b) the holder does not directly own 10% or more of the shares of BioNTech and is subject to income taxes in its state of residence, without being tax-exempt. The restriction of the withholding tax credit does not apply if the holder has beneficially owned the ADSs for at least one uninterrupted year until receipt (*Zufluss*) of the dividends.

In general, as previously discussed, investors should note that it is unclear how the German tax administration will apply the refund process to dividends on the ADSs. Further, such refund is subject to the German anti treaty shopping rule. Generally, this rule requires that the U.S. treaty beneficiary (in case it is a non-German resident company) maintains its own administrative substance and conducts its own business activities. In particular, a foreign company has no right to a full or partial refund to the extent persons holding ownership interests in BioNTech would not be entitled to the refund if they derived the income directly and the gross income realized by the foreign company is not caused by the business activities of the foreign company, and there are either no economic or other considerable reasons for the interposition of the foreign company, or the foreign company does not participate in general commerce by means of a business organization with resources appropriate to its business purpose. However, this shall not apply if the foreign company's principal class of stock is regularly traded in substantial volume on a recognized stock exchange, or if the foreign company is subject to the provisions of the German Investment Tax Act (*Investmentsteuergesetz*). Whether or not and to which extent the anti-treaty shopping rule applies to the ADSs has to be analyzed on a case by case basis taking into account all relevant tests. In addition, the interpretation of these tests is disputed and to date no published decisions of the German Federal Finance Court exist in this regard.

Due to the legal structure of the ADSs, only limited guidance from the German tax authorities exists on the practical application of the refund process with respect to the ADSs and the respective limitations. Recently, the German tax authorities have indicated that for ADR programs (which are considered comparable to ADS programs) a collective tax certificate in connection with a withholding of tax amounts may no longer be issued by the domestic depository of the shares upon request of the foreign depository agents. Rather, individual tax certificates need to be issued which might delay a potential refund procedure. Moreover, the simplified refund procedure based on electronic data exchange (*Datenträgerverfahren*) for claims for reimbursement based on ADRs has been suspended temporarily by the tax authorities.

Taxation of Holders Tax Resident in Germany

This subsection provides an overview of dividend taxation and of capital gains taxation with regard to the general principles applicable to ADS holders that are tax resident in Germany. A holder is a German tax resident if, in case of an individual, he or she maintains a domicile (*Wohnsitz*) or a usual residence (*gewöhnlicher Aufenthalt*) in Germany or if, in case of a corporation, it has its place of management (*Geschäftsleitung*) or registered seat (*Sitz*) in Germany.

The German dividend and capital gains taxation rules applicable to German tax residents require a distinction between ADSs held as private assets (*Privatvermögen*) and ADSs held as business assets (*Betriebsvermögen*).

ADSs as Private Assets (*Privatvermögen*)

If the ADSs are held as private assets by a German tax resident, dividends and capital gains (other than capital gains from the disposition of a Qualifying Participation) are taxed as investment income and are principally subject to 25% German flat income tax on capital income (*Abgeltungsteuer*) (plus a 5.5% solidarity surcharge (*Solidaritätszuschlag*) thereon, resulting in an aggregate rate of 26.375%), which is levied in the form of withholding tax (*Kapitalertragsteuer*). In other words, once deducted, the holder's income tax liability on the dividends will be settled. Dividend payments to the extent funded from BioNTech's tax-recognized contribution account (*steuerliches Einlagekonto*), subject to certain prerequisites, do not form part of the taxable dividend income but should lower the holder's acquisition costs for the ADSs.

Holders of ADSs may apply to have their capital investment income assessed in accordance with the general rules and with an individual's personal income tax rate if this would result in a lower tax burden in which case actually incurred expenses are not deductible. The holder would be taxed on gross personal investment income (including dividends or gains with respect to ADSs), less the saver's allowance of €801 for an individual or €1,602 for a married couple and a registered civil union (*eingetragene Lebenspartnerschaft*) filing taxes jointly. These amounts increase from 2023 onwards to a saver's allowance of €1,000 for an individual or €2,000 for a married couple and a registered civil union (*eingetragene Lebenspartnerschaft*) filing taxes jointly. The deduction of expenses related to the investment income (including dividends or gains with respect to ADSs) is generally not possible for private investors.

Losses resulting from the disposal of ADSs can only be offset against capital gains from the sale of any shares (*Aktien*) and other ADSs. If, however, a holder holds a Qualifying Participation, 60% of any capital gains resulting from the sale and transfer are taxable at the holder's personal income tax rate (plus 5.5% solidarity surcharge thereon). Conversely, 60% of any capital losses are recognized for tax purposes.

Since 2021, the basis for the calculation of the solidarity surcharge (*Solidaritätszuschlag*) has been reduced for certain individual persons being subject to tax assessments (other than withholding taxes), and in certain cases, the solidarity surcharge has been abolished. However, the abolition or reduction of the solidarity surcharge is not applicable to corporations. In addition, the abolition or reduction of the solidarity surcharge will not affect withholding taxes. Solidarity surcharge will still be levied at 5.5% on the full withholding tax amount and withheld accordingly. There will not be any separate refund of such withheld solidarity surcharge (regardless of the aforementioned exemption limits) in case the withholding tax cannot be refunded either.

Church tax generally has to be withheld, if applicable, based on an automatic data access procedure, unless the holder of ADSs has filed a blocking notice (*Sperrvermerk*) with the Federal Central Tax Office. Where church tax is not levied by way of withholding, it is determined by means of income tax assessment.

ADSs as Business Assets (*Betriebsvermögen*)

In case the ADSs are held as business assets, the taxation depends on the legal form of the holder *i.e.*, whether the holder is a corporation or an individual).

Irrespective of the legal form of the holder, dividends are subject to the aggregate withholding tax rate of 26.375%. The withholding tax is generally creditable against the respective holder's corporate income tax or income tax liability. Due to special rules on the restriction of withholding tax credits in respect of dividends, a full withholding tax credit requires that the following three cumulative requirements are met: (i) the holder must qualify as beneficial owner of the ADSs for an uninterrupted minimum holding period of 45 days occurring within a period starting 45 days prior to and ending 45 days after the due date of the dividends, (ii) the holder has to bear at least 70% of the change in value risk related to the ADSs during the minimum holding period as described under (i) of this paragraph and has not entered into (acting by itself or through a related party) hedging transactions which lower the change in value risk for more than 30%, and (iii) the holder must not be obliged to fully or largely compensate directly or indirectly the dividends to third parties. If these requirements are not met, three-fifths of the withholding tax imposed on the dividends must not be credited against the holder's corporate income tax or income tax liability, but may, upon application, be deducted from the holder's tax base for the relevant tax assessment period. A holder that is generally subject to German income tax or corporate income tax and that has received gross dividends without any deduction of withholding tax due to a tax exemption without qualifying for a full tax credit under the aforementioned requirements has to notify the competent local tax office accordingly, has to file withholding tax returns for a withholding tax of 15% in accordance with statutory formal requirements and has to make a payment in the amount of the omitted withholding tax deduction. The special rules on the restriction of withholding tax credit (and the corresponding notification and payment obligations) do not apply to a holder whose overall dividend earnings within an assessment period do not exceed €20,000 or that has been the beneficial owner of the ADSs for at least one uninterrupted year until receipt (*Zufluss*) of the dividends.

To the extent the amount withheld exceeds the income tax liability, the withholding tax will be refunded, provided that certain requirements are met (including the aforementioned requirements).

Special rules apply to credit institutions (*Kreditinstitute*), financial services institutions (*Finanzdienstleistungsinstitute*), financial enterprises (*Finanzunternehmen*), life insurance and health insurance companies, and pension funds.

In principle, dividends that a corporation receives from German or foreign corporations are subject to corporate income tax (and solidarity surcharge thereon) at a rate of 15.825% and also subject to trade tax of between 7.0% and 19.0% depending on the multiplier applied by the relevant municipality. However, with regard to holders in the legal form of a corporation, capital gains are in general effectively 95% tax exempt from corporate income tax (including solidarity surcharge). Dividends are also generally 95% tax exempt from corporate income tax (including solidarity surcharge), *inter alia*, if the holder held at least 10% of the registered share capital (*Grundkapital oder Stammkapital*) of BioNTech at the beginning of the calendar year, or Qualifying Dividends. Five percent of the capital gains and five percent of the Qualifying Dividends are treated as non-deductible business expenses, respectively, and, as such, are subject to corporate income tax (including solidarity surcharge); actual business expenses incurred to generate dividends may be deducted. The acquisition of a participation of at least 10% in the course of a calendar year is deemed to have occurred at the beginning of such calendar year for the determination of whether a dividend is a Qualifying Dividend. Participations in the share capital of BioNTech held through a partnership, including co-entrepreneurships (*Mitunternehmenschaften*), are attributable to the respective partner only on a pro rata basis at the ratio of its entitlement to the profits of the partnership.

Capital gains and dividend income of a German tax resident corporation are generally subject to German trade tax of between 7.0% and 19.0% depending on the multiplier applied by the relevant municipality. The aforementioned 95% exemption for capital gains generally applies also for trade tax purposes. However, the amount of any dividends after deducting business expenses related to the dividends is not subject to trade tax if the corporation held at least 15% of BioNTech's registered share capital at the beginning of the relevant tax assessment period. In this case, the aforementioned exemption of 95% of the dividend income also applies for trade tax purposes. Losses from the sale of ADSs are generally not tax deductible for corporate income tax and trade tax purposes.

With regard to individuals holding ADSs as business assets, 60% of dividends and capital gains are taxed at the individual's personal income tax rate (plus 5.5% solidarity surcharge thereon). Correspondingly, only 60% of business expenses related to the dividends and capital gains as well as losses from the sale of ADSs are principally deductible for

income tax purposes. Since 2021, the basis for the calculation of the solidarity surcharge *Solidaritatzuschlag*) has been reduced for certain individual persons being subject to tax assessments (other than withholding taxes), and in certain cases, the solidarity surcharge has been abolished, subject to the limitations described above in “—ADSs as Private Assets (*Privatvermogen*)”. The dividend income and 60% of the capital gains are generally subject to trade tax, which is fully or partly creditable against the individual’s personal income tax by a lump-sum method. Dividends (after deduction of business expenses economically related thereto) are exempt from trade tax if the holder held at least 15% of BioNTech’s registered share capital at the beginning of the relevant tax assessment period.

German Inheritance and Gift Tax (*Erbschaft- und Schenkungsteuer*)

The transfer of ADSs to another person by inheritance or gift generally should be subject to German inheritance and gift tax only if:

- (i) the decedent or donor or heir, beneficiary or other transferee (a) maintained his or her domicile or a usual residence in Germany, (b) had its place of management or registered office in Germany at the time of the transfer, (c) is a German citizen who has spent no more than five consecutive years outside of Germany without maintaining a domicile in Germany or (d) is a German citizen who serves for a German entity established under public law and is remunerated for his or her service from German public funds (including family members who form part of such person’s household, if they are German citizens) and is only subject to estate or inheritance tax in his or her country of domicile or usual residence with respect to assets located in such country (special rules apply to certain former German citizens who neither maintain a domicile nor have their usual residence in Germany);
- (ii) at the time of the transfer, the ADSs are held by the decedent or donor as business assets forming part of a permanent establishment in Germany or for which a permanent representative in Germany has been appointed; or
- (iii) the ADSs subject to such transfer form part of a portfolio that represents at the time of the transfer 10% or more of the registered share capital of BioNTech and that has been held directly or indirectly by the decedent or donor, either alone or together with related persons.

The Agreement between the Federal Republic of Germany and the United States of America for the avoidance of double taxation with respect to taxes on inheritances and gifts as of December 21, 2000 (*Abkommen zwischen der Bundesrepublik Deutschland und den Vereinigten Staaten von Amerika zur Vermeidung der Doppelbesteuerung auf dem Gebiet der Nachlass-, Erbschaft- und Schenkungssteuern in der Fassung vom 21. Dezember 2000*), hereinafter referred to as the “United States-Germany Inheritance and Gifts Tax Treaty,” provides that the German inheritance tax or gift tax can, with certain restrictions, only be levied in the cases of (i) and (ii) above. Special provisions apply to certain German citizens living outside of Germany and former German citizens.

Other Taxes

No German transfer tax, value-added tax, stamp duty or similar taxes are assessed on dividend payments.

Material United States Federal Income Tax Considerations

The following discussion describes material U.S. federal income tax considerations relating to the acquisition, ownership and disposition of ADSs by a U.S. Holder (as defined below) that acquires our ADSs and holds them as a capital asset. This discussion is based on the tax laws of the United States, including the Internal Revenue Code of 1986, as amended, or the Code, Treasury regulations promulgated or proposed thereunder, and administrative and judicial interpretations thereof, all as in effect on the date hereof. These tax laws are subject to change, possibly with retroactive effect, and subject to differing interpretations that could affect the tax consequences described herein. This section does not address the treatment of a non-U.S. holder, nor does it address the tax treatment under the laws of any state, local or foreign taxing jurisdiction.

For purposes of this discussion, a “U.S. Holder” is a beneficial owner of our ADSs that, for U.S. federal income tax purposes, is:

- an individual who is a citizen or resident of the United States;
- a domestic corporation (or other entity taxable as a corporation);

- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (i) a court within the United States is able to exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all substantial decisions of the trust or (ii) a valid election under the Treasury regulations is in effect for the trust to be treated as a U.S. person.

This discussion does not address all aspects of U.S. federal income taxation that may be applicable to U.S. Holders in light of their particular circumstances or status (including, for example, banks and other financial institutions, insurance companies, broker and dealers in securities or currencies, traders that have elected to mark securities to market, regulated investment companies, real estate investment trusts, partnerships or other pass-through entities, corporations that accumulate earnings to avoid U.S. federal income tax, tax-exempt organizations, pension plans, persons that hold our shares as part of a straddle, hedge or other integrated investment, persons subject to alternative minimum tax or whose "functional currency" is not the U.S. dollar).

If a partnership (including any entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our ADSs, the tax treatment of a person treated as a partner in the partnership for U.S. federal income tax purposes generally will depend on the status of the partner and the activities of the partnership. Partnerships (and other entities or arrangements so treated for U.S. federal income tax purposes) and their partners should consult their own tax advisors.

In general, and taking into account the earlier assumptions, for U.S. federal income and German tax purposes, a holder of ADSs will be treated as the owner of the shares represented by those ADSs. Exchanges of shares for ADSs, and ADSs for shares, generally will not be subject to U.S. federal income or to German tax.

This discussion addresses only U.S. Holders and does not discuss any tax considerations other than U.S. federal income tax considerations. Prospective investors are urged to consult their own tax advisors regarding the U.S. federal, state and local, and foreign tax consequences of the purchase, ownership, and disposition of ADSs.

Dividends

Under the U.S. federal income tax laws, and subject to the passive foreign investment company, or PFIC, rules discussed below, the gross amount of any dividend we pay out of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) is includible in income for a U.S. Holder and subject to U.S. federal income taxation. Dividends paid to a noncorporate U.S. Holder that constitute qualified dividend income will be taxable at a preferential tax rate applicable to long-term capital gains, provided that the U.S. Holder holds the ADSs for more than 60 days during the 121-day period beginning 60 days before the ex-dividend date and meets other holding period requirements. Dividends we pay with respect to the ADSs generally will be qualified dividend income.

A U.S. Holder must include any German tax withheld as part of the gross dividend payment, as described above under "—German Taxation—General Rules for the Taxation of Holders Not Tax Resident in Germany," even though the holder does not in fact receive it. The dividend is taxable to the holder when the depository receives the dividend, actually or constructively. Because we are not a U.S. corporation, the dividend will not be eligible for the dividends-received deduction generally allowed to U.S. corporations in respect of dividends received from other U.S. corporations. The amount of the dividend distribution includible in U.S. Holder's income will be the U.S. dollar value of the Euro payments made, determined at the spot Euro/U.S. dollar rate on the date the dividend distribution is includible in income, regardless of whether the payment is in fact converted into U.S. dollars. Generally, any gain or loss resulting from currency exchange fluctuations during the period from the date the dividend payment is included in income to the date the payment is converted into U.S. dollars will be treated as ordinary income or loss and will not be eligible for the special tax rate applicable to qualified dividend income. The gain or loss generally will be income or loss from sources within the United States for foreign tax credit limitation purposes.

To the extent a distribution with respect to ADSs exceeds our current or accumulated earnings and profits, as determined under U.S. federal income tax principles, the distribution will be treated, first, as a tax-free return of the U.S. Holder's investment, up to the holder's adjusted tax basis in its ADSs, and, thereafter, as capital gain, which is subject to the tax treatment described below in "—Gain on Sale, Exchange or Other Taxable Disposition."

Subject to certain limitations, the German tax withheld in accordance with the Treaty and paid over to the German taxing authority will be creditable or deductible against a U.S. Holder's U.S. federal income tax liability. To the extent a

refund of the tax withheld is available to a U.S. Holder under German law or under the Treaty, the amount of tax withheld that is refundable will not be eligible for credit against a U.S. Holder's U.S. federal income tax liability. See “—German Taxation—Withholding Tax Refund for U.S. Treaty Beneficiaries” above for the procedures for obtaining a tax refund.

Gain On Sale, Exchange or Other Taxable Disposition

Subject to the PFIC rules described below under “—Passive Foreign Investment Company Considerations”, a U.S. Holder that sells, exchanges or otherwise disposes of ADSs in a taxable disposition generally will recognize capital gain or loss for U.S. federal income tax purposes equal to the difference between the U.S. dollar value of the amount realized and the holder's tax basis, determined in U.S. dollars, in the ADSs. Gain or loss recognized on such a sale, exchange or other disposition of ADSs generally will be long-term capital gain if the U.S. Holder's holding period in the ADSs exceeds one year. Long-term capital gains of non-corporate U.S. Holders are taxed generally at preferential rates. The gain or loss generally will be income or loss from sources within the United States for foreign tax credit limitation purposes. A U.S. Holder's ability to deduct capital losses is subject to limitations.

Passive Foreign Investment Company Considerations

We believe that we were a PFIC for our 2023 taxable year. Because the determination of our PFIC status is made annually based on the factual tests described below, however, we cannot estimate with certainty at this stage whether or not we are likely to be treated as a PFIC in the current taxable year or any future taxable years. In particular, the total value of our asset test generally will be calculated taking into account the market price of our ADSs or ordinary shares. This value has fluctuated considerably in the past, and may fluctuate considerably in the future. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the IRS will agree with our conclusion regarding our PFIC status.

We are treated as a PFIC for any taxable year in which at least 75% of our gross income is “passive income” or at least 50% of our gross assets during the taxable year (based on the average of the fair market values of the assets determined at the end of each quarterly period) are assets that produce or are held for the production of passive income. Passive income for this purpose generally includes, among other things, dividends, interest, rents, royalties, gains from commodities and securities transactions, and gains from assets that produce passive income. In addition, cash and short-term investment are treated as passive assets regardless of the fact that they may not produce any income. Rents and royalties received from unrelated parties in connection with the active conduct of a trade or business are not considered passive income for purposes of the PFIC test. In determining whether we are a PFIC, a pro rata portion of the income and assets of each corporation in which we own, directly or indirectly, at least a 25% interest (by value) is taken into account.

If we are classified as a PFIC in any taxable year, a U.S. Holder will be subject to special rules with respect to distributions on and sales, exchanges and other dispositions of the ADSs. In addition, a U.S. Holder that holds the ADSs at any time during a taxable year in which we are classified as a PFIC generally will continue to have to treat such ADSs as ADSs in a PFIC, even if we no longer satisfy the income and asset tests described above, unless the U.S. Holder elects to recognize gain, which will be taxed under the excess distribution rules described below as if such ADSs had been sold on the last day of the last taxable year for which we were a PFIC.

Certain elections by a U.S. Holder, described below, generally alleviate some of the adverse consequences of the excess distribution rules and would result in an alternative treatment of the ADSs, as described below.

A U.S. Holder of PFIC shares must generally file an annual information return on IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) and will make any of the elections described below such Form attached to a timely filed U.S. federal income tax return (including available extensions). The failure to file IRS Form 8621 could result in an extension of the statute of limitations with respect to U.S. federal income tax.

Excess Distribution Rules. If we are a PFIC with respect to a U.S. Holder, then unless such U.S. Holder makes one of the elections described below, a special tax regime will apply to the U.S. Holder with respect to (i) any “excess distribution” (generally, aggregate distributions in any year that are greater than 125% of the average annual distribution received by the holder in the shorter of the three preceding years or the holder's holding period for the ADSs) and (ii) any gain realized on the sale or other disposition of the ADSs. Under this regime, any excess distribution and realized gain is treated as ordinary income and is subject to tax as if (a) the excess distribution or gain had been realized ratably over the U.S. Holder's holding period, (b) the amount deemed realized in each year had been subject to tax in each year of that

holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which is subject to tax at the U.S. Holder's regular ordinary income rate for the current year and is not subject to the interest charge discussed below), and (c) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. If we are a PFIC, this tax treatment for U.S. Holders applies also to indirect distributions and gains deemed realized by U.S. Holders in respect of stock of any of our subsidiaries determined to be PFICs. In addition, dividend distributions do not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under "—Taxation of Dividends."

Elective Alternative Treatment. If we are a PFIC, the rules above do not apply to a U.S. Holder that makes an election to treat ADSs as stock of a "qualified electing fund" or QEF. We intend to provide to U.S. Holders the required information to make a valid QEF election and expect to provide that information after April 15, 2024 and before October 15, 2024 on our corporate website. As a result, a U.S. Holder is expected to be able to make the QEF election with respect to its ADSs with an extension to file its U.S. federal income tax return. A U.S. Holder that makes a QEF election is required to include in income its pro rata share of our ordinary earnings and net capital gain as ordinary income and long-term capital gain, respectively, subject to a separate election to defer payment of taxes, which deferral is subject to an interest charge. A U.S. Holder makes a QEF election generally by attaching a completed IRS Form 8621 to a timely filed United States federal income tax return for the year beginning with which the QEF election is to be effective (taking into account any extensions). A QEF election can be revoked only with the consent of the IRS. We intend to annually provide or make available the information required for a U.S. Holder to make a valid QEF election.

The rules above also do not apply to a U.S. Holder that makes a "mark-to-market" election with respect to the ADSs. This election is available with respect to the ADSs only if they meet certain minimum trading requirements to be considered "marketable stock" for purposes of the PFIC rules. Generally, shares or ADSs are treated as marketable stock if they are "regularly traded" on a "qualified exchange" within the meaning of applicable U.S. Treasury Regulations. ADSs generally will be considered regularly traded during any calendar year during which they are traded, other than in *de minimis* quantities, on at least 15 days during each calendar quarter. Any trades that have as their principal purpose meeting this requirement will be disregarded. Our ADSs will be marketable stock as long as they remain listed on the Nasdaq Global Select Market and are traded regularly.

A U.S. Holder that makes a valid mark-to-market election for the first tax year in which the holder holds (or is deemed to hold) ADSs and for which we are a PFIC will be required to include each year an amount equal to the excess, if any, of the fair market value of such ADSs the holder owns as of the close of the taxable year over the holder's adjusted tax basis in such ADSs. The U.S. Holder will be entitled to a deduction for the excess, if any, of the holder's adjusted tax basis in the ADSs over the fair market value of such ADSs as of the close of the taxable year, but only to the extent of any net mark-to-market gains with respect to such ADSs included by the U.S. Holder under the election for prior taxable years. The U.S. Holder's basis in such ADSs will be adjusted to reflect the amounts included or deducted pursuant to the election. Amounts included in income pursuant to a mark-to-market election, as well as gain on the sale, exchange or other taxable disposition of such ADSs, will be treated as ordinary income. The deductible portion of any mark-to-market loss, as well as loss on a sale, exchange or other disposition of ADSs to the extent that the amount of such loss does not exceed net mark-to-market gains previously included in income, will be treated as ordinary loss.

The mark-to-market election applies to the taxable year for which the election is made and all subsequent taxable years, unless the shares cease to be treated as marketable stock for purposes of the PFIC rules or the IRS consents to its revocation. The excess distribution rules described above generally will not apply to a U.S. Holder for tax years for which a mark-to-market election is in effect. However, if we are a PFIC for any year in which the U.S. Holder owns the ADSs but before a mark-to-market election is made, the interest charge rules described above applies to any mark-to-market gain recognized in the year the election is made.

U.S. Holders are urged to consult their tax advisors as to our status as a PFIC, and the tax consequences to them if we were a PFIC, including the reporting requirements and the desirability of making, and the availability of, a QEF election or a mark-to-market election with respect to the ADSs.

Medicare Tax

Non-corporate U.S. Holders that are individuals, estates or trusts and whose income exceeds certain thresholds generally are subject to a 3.8% tax on all or a portion of their net investment income, which may include their gross dividend income and net gains from the disposition of ADSs. A U.S. person that is an individual, estate or trust is

encouraged to consult its tax advisors regarding the applicability of this Medicare tax to its income and gains in respect of any investment in ADSs.

Information Reporting with Respect to Foreign Financial Assets

Individual U.S. Holders may be subject to certain reporting obligations on IRS Form 8938 (Statement of Specified Foreign Financial Assets) with respect to the ADSs for any taxable year during which the U.S. Holder's aggregate value of these and certain other "specified foreign financial assets" exceed a threshold amount that varies with the filing status of the individual. This reporting obligation also applies to domestic entities formed or availed of to hold, directly or indirectly, specified foreign financial assets, including the ADSs. Significant penalties can apply if U.S. Holders are required to make this disclosure and fail to do so.

U.S. Holders who acquire ADSs for cash may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) with the IRS and to supply certain additional information to the IRS if (i) immediately after the transfer, the U.S. Holder owns directly or indirectly (or by attribution) at least 10% of our total voting power or value or (ii) the amount of cash transferred to us in exchange for ADSs, when aggregated with all related transfers under applicable regulations, exceeds \$100,000. Substantial penalties may be imposed on a U.S. Holder that fails to comply with this reporting requirement.

Information Reporting and Backup Withholding

In general, information reporting, on IRS Form 1099, will apply to dividends in respect of ADSs and the proceeds from the sale, exchange or redemption of ADSs that are paid to a holder of ADSs within the United States (and in certain cases, outside the United States), unless such holder is an exempt recipient such as a corporation. Backup withholding (currently at a 24% rate) may apply to such payments if a holder of ADSs fails to provide a taxpayer identification number (generally on an IRS Form W-9) or certification of other exempt status or fails to report in full dividend and interest income.

Backup withholding is not an additional tax. A U.S. Holder generally may obtain a refund of any amounts withheld under the backup withholding rules that exceed the U.S. Holder's income tax liability by filing a refund claim with the IRS.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the informational requirements of the Exchange Act. Accordingly, we are required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. The SEC maintains an Internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

We also make available on our website, free of charge, our Annual Report and the text of our reports on Form 6-K, including any amendments to these reports, as well as certain other SEC filings, as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Our website address is www.biontech.de. The information contained on our website is not incorporated by reference in this Annual Report and our website address is included in this Annual Report as an inactive textual reference only.

Statements contained in this Annual Report regarding the contents of any contract or other document are not necessarily complete, and, where the contract or other document is an exhibit to the Annual Report, each of these statements is qualified in all respects by the provisions of the actual contract or other documents.

I. Subsidiary Information

Not applicable.

Item 11. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to various risks in relation to financial instruments, including counterparty risk and currency risk. Our risk management is coordinated by our Management Board. We do not engage in the trading of financial assets for speculative purposes. The most significant financial risks to which we are exposed include the risks discussed below.

Counterparty Risk

In order to mitigate default risks within our asset management portfolio, we diversify our cash investments among various counterparties and instruments that have an investment grade rating. Transactions are carried out within the limits approved by the treasury committee.

Foreign Currency Risk

We publish our consolidated financial statements in Euro. Revenue and expenses incurred in U.S. dollars will be translated into Euro when they are reported in our consolidated financial statements. We are subject to currency risks, as our income and expenditures are denominated in Euro and the U.S. dollar. As such, we are exposed to exchange rate fluctuations between these currencies. Cash inflows denominated in U.S. dollar mainly result from generating proceeds under our collaboration agreements. Our commercial revenues are primarily collaboration revenues from earnings based on our partners' gross profit, which is shared under the respective collaboration agreements and represents payments we receive in U.S. dollar. Cash outflows dominated in U.S. dollar mainly result from amounts spent on research and development activities and license obligations as well as expanding our global footprint further. With the aim of preserving capital, surplus liquidity is mainly invested in domestic currency investments as exchange rate fluctuations can reduce the value of our financial positions. We limit the effects of the identified risks by means of a coordinated and consistently implemented risk strategy. Besides applying natural hedging relationships where possible, foreign exchange forward contracts are concluded, as a matter of principle, as instruments to mitigate foreign currency exchange risk associated with foreign currency-denominated payments.

For further disclosures relating to foreign exchange forward contracts, see Note 12 to our consolidated financial statements included elsewhere in this Annual Report.

Notwithstanding our efforts to mitigate some foreign currency exchange risks, there can be no assurance that our hedging activities will adequately protect us against the risks associated with foreign currency fluctuations. We believe the counterparties to our foreign currency forward contracts are creditworthy multinational commercial banks. While we believe the risk of counterparty nonperformance is not material, a sustained decline in the financial stability of financial institutions as a result of disruption in the financial markets could affect our ability to secure creditworthy counterparties for our foreign currency hedging programs. Therefore, developments on the financial markets are continuously monitored to enable us to respond to exceptional events at short notice.

As a result, any substantial future appreciation or decline of the U.S. dollar against the Euro could have a material effect on our revenue and profitability. As an example, if the U.S. dollar weakens by 5% against the Euro, financial assets and liabilities denominated in U.S. dollar as of December 31, 2023 would have an effect of €39.2 million on our profit before tax.

For additional information about our quantitative and qualitative market risks, see Note 12 to the consolidated financial statements.

Item 12. Description of Securities Other than Equity Securities

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Fees and Expenses

Persons depositing or withdrawing shares or ADS holders must pay:

\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)

\$.05 (or less) per ADS

A fee equivalent to the fee that would be payable if securities distributed to an ADS holder had been shares and the shares had been deposited for issuance of ADSs

\$.05 (or less) per ADS per calendar year

Registration or transfer fees

Expenses of the depositary

Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes

Any charges incurred by the depositary or its agents for servicing the deposited securities

For:

Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property

Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates

Any cash distribution to ADS holders

Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders

Depositary services

Transfer and registration of shares on our share register to or from the name of the depositary or its agent when an ADS holder deposits or withdraws shares

Cable and facsimile transmissions (when expressly provided in the deposit agreement)

Converting foreign currency to U.S. dollars

As necessary

As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of

securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by, or affiliated with, the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

Payment of Taxes

ADS holders will be responsible for any taxes or other governmental charges payable on their ADSs or on the deposited securities represented by any of their ADSs. The depositary may refuse to register any transfer of ADS holders ADSs or allow him or her to withdraw the deposited securities represented by his or her ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by his or her ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, if appropriate, it will reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

Not applicable.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

Not applicable.

Item 15. Controls and Procedures

Disclosure Controls and Procedures

As required by Rule 13a-15 under the Exchange Act, management, including our Chief Executive Officer (CEO) and our Chief Financial Officer (CFO), has performed an evaluation of the effectiveness of our disclosure controls and procedures. Disclosure controls and procedures refer to controls and other procedures designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include, without limitations, controls and procedures designed to ensure that information required to be disclosed by us in our reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding our required disclosures.

Based on the foregoing, our CEO and CFO have concluded that, as of the end of the period covered by this annual report, our disclosure controls and procedures were effective in ensuring that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in by the SEC's rules and forms, and that the information required to be disclosed by us in the reports

that we file or submit under the Exchange Act is accumulated and communicated to our management to allow timely decisions regarding required disclosure.

Management’s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Our internal control over financial reporting is a process designed by or under the supervision of the Chief Financial Officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with International Financial Reporting Standards as issued by the IASB.

No system of internal control over financial reporting, including one determined to be effective, may prevent or detect all misstatements. It can provide only reasonable assurance regarding financial statement preparation and presentation. Also, projections of the results of any evaluation of the effectiveness of internal control over financial reporting into future periods are subject to inherent risk. The relevant controls may become inadequate due to changes in circumstances or the degree of compliance with the underlying policies or procedures may deteriorate.

Our management assessed the effectiveness of the Company’s internal control over financial reporting as of December 31, 2023. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in “Internal Control - Integrated Framework (2013)”.

Based on this assessment, our management has determined that the Company’s internal control over financial reporting as of December 31, 2023 is effective

As permitted by the SEC, the Company has elected to exclude an assessment of the internal controls of acquisitions made during the year ended December 31, 2023, namely the acquisition of InstaDeep. InstaDeep’s impact on our revenue and profit for the period has been immaterial (see Note 5 to the consolidated financial statements).

Attestation Report of the Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2023 has been audited by EY GmbH & Co. KG Wirtschaftsprüfungsgesellschaft, an independent registered public accounting firm. Their report is included on page F-2. EY GmbH & Co. KG Wirtschaftsprüfungsgesellschaft is a member of the Chamber of Public Accountants (*Wirtschaftsprüferkammer*), Berlin, Germany.

Changes in Control over Financial Reporting

During the period covered by this report a new ERP System was implemented. The internal controls over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Securities and Exchange Act of 1934) were reviewed and updated to cover all risk inherent with the change. The new control set was assessed as part of the overall management assessment and determined as effective as of December 31, 2023.

Item 16. [Reserved]

Item 16A. Audit Committee Financial Expert

Our Audit Committee for the year ended December 31, 2023 consisted of Anja Morawietz. (Chair), Rudolf Staudigl and Ulrich Wandschneider. All members of the Audit Committee qualify as “independent directors” as such term is defined in Rule 10A-3 under the Exchange Act and Nasdaq Rule 5605. Additionally, our Supervisory Board has determined that each of Anja Morawietz, Rudolf Staudigl and Ulrich Wandschneider qualifies as “audit committee financial expert” as that term is defined under the Exchange Act.

Item 16B. Code of Ethics

We have adopted a Code of Business Conduct & Ethics, or Code of Conduct, which outlines the principles of legal and ethical business conduct under which we do business. The Code of Conduct applies to all of our Supervisory Board members, Management Board members, directors of our subsidiaries and employees. The full text of the Code of Conduct is available on our website at <https://www.biontech.de>. The information and other content appearing on our website are not

part of this Annual Report and our website address is included in this Annual Report as an inactive textual reference only. Any amendments or waivers from the provisions of the Code of Conduct for members of our Supervisory or Management Boards will be made only after approval by our Supervisory Board and will be disclosed on our website promptly following the date of such amendment or waiver.

Item 16C. Principal Accountant Fees and Services

EY GmbH & Co. KG Wirtschaftsprüfungsgesellschaft, or EY, has served as our independent registered public accounting firm for the years ended December 31, 2023, December 31, 2022, December 31, 2021 for which audited financial statements appear in this Annual Report.

The following table sets out the aggregate fees for professional audit services and other services rendered by EY in the periods indicated:

<i>(in millions €)</i>	Years ended December 31,	
	2023	2022
Audit fees	3.2	2.9
Audit-related fees	0.3	0.4
Tax fees	0.1	0.2
All other fees	—	0.2
Total fees for professional audit services and other services	3.6	3.7

In the year ended December 31, 2023, audit fees related to professional services associated with the integrated audit of our consolidated financial statements and our internal control over financial reporting as set out in this Annual Report, professional services associated with interim reviews, audit fees related to the remuneration report and professional services related to our statutory and regulatory filings for our subsidiaries. In the year ended December 31, 2022, audit fees related to professional services associated with the integrated audit of our consolidated financial statements and our internal control over financial reporting as set out in this Annual Report, professional services associated with interim reviews, audit fees related to the remuneration report and professional services related to our statutory and regulatory filings for our subsidiaries.

In the year ended December 31, 2023, audit-related fees were attributable to assurance and related services including attest related services and accounting consultations. In the year ended December 31, 2022, audit-related fees were attributable to assurance and related services including attest related services and accounting consultations.

In the year ended December 31, 2023, tax service fees were billed for services in conjunction with transactions, especially with our financing and deal transactions. In the year ended December 31, 2022, tax service fees billed for services in conjunction with transactions, especially with our financing and deal transactions.

In the year ended December 31, 2023, other fees were comprised of fees for services for consultancy services around management compensation. In the year ended December 31, 2022 other fees were comprised of fees for services for grant applications and consultancy services around management compensation.

The Audit Committee evaluates the qualifications, independence and performance of the independent auditor as well as pre-approves and reviews the audit and non-audit services to be performed by the independent auditor. The external audit plan and fees for professional audit services and other services rendered by EY for the years ended December 31, 2023 and 2022 were approved by the Audit Committee. The Audit Committee monitors compliance with the German and U.S. rules on non-audit services provided by an independent registered public accounting firm.

Item 16D. Exemptions from the Listing Standards for Audit Committees

Please see “Board Practices—Supervisory Board Practices—Audit Committee” in Item 6C of this Annual Report for the information required by this Item 16D.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

In March 2022, our Management Board and Supervisory Board authorized the 2022 share repurchase program of ADSs, pursuant to which we were permitted to repurchase ADSs, each representing one ordinary share, with a value of up to \$1.5 billion a two-year period, commencing on May 2, 2022. The first tranche of our 2022 share repurchase program of ADSs, with a value of up to \$1.0 billion, concluded on October 10, 2022. The second tranche with a value of up to \$0.5 billion commenced on December 7, 2022 and concluded on March 17, 2023.

In March 2023, our Management Board and Supervisory Board authorized the 2023 share repurchase program, under which we were permitted to purchase ADSs, each representing one ordinary share, with a value of up to \$0.5 billion, which started June 2, 2023 and concluded on September 18, 2023.

The following repurchases under the programs occurred:

2022 Program first tranche (\$1.0 billion)

Period	Number of ADSs purchased	Average price paid per ADS	Total number of ADSs purchased	Approximate value of ADSs that may yet be purchased (in millions)
May 2022	917,988	\$151.76 (€143.99)	917,988	\$860.7 (€867.8)
June 2022	1,160,219	\$140.82 (€133.35)	2,078,207	\$697.3 (€713.1)
July 2022	519,320	\$162.03 (€159.40)	2,597,527	\$613.2 (€630.3)
August 2022	1,666,515	\$149.08 (€148.24)	4,264,042	\$364.8 (€383.3)
September 2022	2,280,988	\$135.95 (€137.66)	6,545,030	\$54.6 (€69.3)
October 2022	400,483	\$136.37 (€139.09)	6,945,513	— (—)
Total	6,945,513			

2022 Program second tranche (\$0.5 billion)

Period	Number of ADSs purchased	Average price paid per ADS	Total number of ADSs purchased	Approximate value of ADSs that may yet be purchased (in millions)
January 2023	618,355	\$142.26 (€131.12)	618,355	\$412.0 (€418.9)
February 2023	857,620	\$138.05 (€129.06)	1,475,975	\$293.6 (€308.2)
March 2023	745,196	\$128.49 (€121.08)	2,221,171	\$197.9 (€218.0)
Total	2,221,171			

Program 2023 (\$0.5 billion)

Period	Number of ADSs purchased	Average price paid per ADS	Total number of ADSs purchased	Approximate value of ADSs that may yet be purchased (in millions)
June 2023	1,532,685	\$108.92 (€100.45)	1,532,685	\$333.1 (€346.0)
July 2023	1,738,061	\$107.92 (€97.57)	3,270,746	\$145.5 (€176.4)
August 2023	1,261,706	\$105.07 (€95.85)	4,532,452	\$12.9 (€55.5)
September 2023	114,513	\$112.22 (€105.07)	4,646,965	— (—)
Total	4,646,965			

All purchases disclosed in the tables above were purchased under Rule 10b5-1 trading plans pursuant to such share repurchase programs.

In total 9,166,684 ADSs were repurchased under the 2022 program at an average price of \$142.05 (€138.37), for total consideration of \$1,302.0 million (€1,268.4 million). For the 2023 program, in total 4,646,965 ADSs were repurchased at an average price of \$107.58 (€98.24), for total consideration of \$500.0 million (€456.5 million).

Item 16F. Change in Registrant’s Certifying Accountant

Not applicable.

Item 16G. Corporate Governance

German Corporate Governance Code

The German Corporate Governance Code, or the Corporate Governance Code, was originally published by the German Federal Ministry of Justice (*Bundesministerium der Justiz*) in 2002. The version currently in effect, dated April 28, 2022, was published in the German Federal Gazette *Bundesanzeiger* on June 27, 2022. The Corporate Governance Code contains principles (*Grundsätze*), recommendations (*Empfehlungen*) and suggestions (*Anregungen*) relating to the management and supervision of German companies that are listed on a stock exchange. It follows internationally and nationally recognized standards for good and responsible corporate governance. The purpose of the Corporate Governance Code is to make the German system of corporate governance transparent for investors. The Corporate Governance Code includes corporate governance principles, recommendations and suggestions with respect to shareholders and shareholders’ meetings, the management and supervisory boards, transparency, accounting policies and auditing.

There is no obligation to comply with the recommendations or suggestions of the Corporate Governance Code. The German Stock Corporation Act (*Aktiengesetz*) requires only that the management board and supervisory board of a German company listed on a trading facility (such as a stock exchange) which is regulated and supervised by government authorities issue an annual declaration that either (i) states that the company has complied with the recommendations of the Corporate Governance Code or (ii) lists the recommendations that the company has not complied with and explains its reasons for deviating from the recommendations of the Corporate Governance Code (*Entsprechenserklärung*). In addition, a listed company is also required to state in this annual declaration whether it intends to comply with the recommendations or list the recommendations it does not plan to comply with in the future. These declarations must be made accessible to shareholders at all times. If the company changes its policy on certain recommendations between such annual declarations, it must disclose this fact and explain its reasons for deviating from the recommendations. Non-compliance with suggestions contained in the Corporate Governance Code need not be disclosed.

Our Management Board and Supervisory Board comply with the Corporate Governance Code except for such provisions which are listed explicitly in the annual declaration and for which they provide an explanation of non-compliance.

Differences in Corporate Law

The applicable provisions of the SE Regulation in conjunction with the German Stock Corporation Act as applied to a European stock corporation that has its legal seat in Germany differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the SE Regulation in conjunction with the German Stock Corporation Act applicable to us and the General Corporation Law of the State of Delaware relating to shareholders’ rights and protections. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Delaware law and European and German law.

European Union/Federal Republic of Germany

Delaware

Board System

A European stock corporation may choose to have a two-tier board structure composed of the Management Board (*Vorstand*) and the Supervisory Board (*Aufsichtsrat*). We have chosen this structure.

The Management Board is responsible for running the company's affairs and representing the company in dealings with third parties.

The Supervisory Board of a European stock corporation under German law has a control and supervisory function. The Supervisory Board does not actively manage the company but certain Management Board actions require the approval of the Supervisory Board.

Under Delaware law, a corporation has a unitary board structure, and it is the responsibility of the board of directors to appoint and oversee the management of the corporation on behalf of and in the best interests of the stockholders of the corporation.

Management is responsible for running the corporation and overseeing its day-to-day operations.

Appointment and Number of Directors

Under applicable European and German law, a European stock corporation governed by German law with a share capital of at least €3 million generally must have at least two members on its Management Board and the number of members shall be determined by or in the manner provided in the company's articles of association.

The Supervisory Board must consist of at least three but—depending on the share capital—no more than 21 Supervisory Board members, whereby the number of Supervisory Board members must be divisible by three if this is necessary for the fulfilment of co-determination requirements. The articles of association of the company must specify if the Supervisory Board has more than three members.

Supervisory Board members are either appointed by the shareholders' meeting or delegated by one or more individual shareholders if so provided for in the company's articles of association. If the Supervisory Board consists of fewer members than is required to meet the quorum for resolutions (either statutory or pursuant to the company's articles of association), a competent court may appoint additional members as needed to meet the quorum. The provisions of German law in relation to employees' co-determination do not apply to the Company.

Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws.

Removal of Directors

Members of the Management Board of a European stock corporation are appointed by the Supervisory Board for a maximum period of six years with an opportunity to be reelected. The articles of association may provide for a shorter term which in our case is up to five years. The members of the Management Board may be reelected, even repeatedly. The Supervisory Board may remove a member of the Management Board prior to the expiration of his or her term only for cause, such as gross breach of duties (*grobe Pflichtverletzung*), the inability to manage the business properly (*Unfähigkeit zur ordnungsgemäßen Pflichtausübung*) or a vote of no-confidence during the shareholders' meeting (*Vertrauensentzug*). The shareholders themselves are not entitled to appoint or dismiss the members of the Management Board.

Under European law, a member of the Supervisory Board of a company may be elected for a term of up to six years. The articles of association may provide for a shorter term. Our Supervisory Board members are, if the general meeting does not resolve on a shorter term, elected for a period up to the end of the general meeting deciding on the discharge for the fourth financial year after the election. Reelection, including repeated reelection, is permissible. Members of the Supervisory Board may be removed with or without cause by way of a general meeting resolution, with the applicable majority requirement depending on the relevant company's articles of association.

Under Delaware law, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board of directors is classified, stockholders may effect such removal only for cause; or (ii) in the case of a corporation having cumulative voting, if less than the entire board of directors is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.

Vacancies on the Board of Directors	<p>Under the law, vacant positions on the Management Board are filled by the Supervisory Board in accordance with the general rules of appointment, which provide that vacancies are filled by the simple majority of votes of Supervisory Board members present or represented by proxy at the vote (with, under certain circumstances, the chairman having a casting vote), unless otherwise provided by the company's articles of association. In case of emergencies, a vacant position on the Management Board may be filled by an individual appointed by the court. Vacant positions on the Supervisory Board are filled in accordance with the general rules of appointment.</p>	<p>Under Delaware law, vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) or by a sole remaining director unless (i) otherwise provided in the certificate of incorporation or by-laws of the corporation or (ii) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case a majority of the other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.</p>
Annual General Meeting	<p>A European stock corporation, which is governed by German law, must hold an annual shareholders' meeting within six months of the end of its fiscal year. The annual shareholders' meeting must be held at a location determined by the articles of association. If the articles of association do not provide for a specific location, the shareholders' meeting shall be held at the company's seat or, if applicable, at the venue (in Germany) where its shares are listed. Under the articles of association, the Management Board is authorized to provide for the Annual General Meeting to be held without the physical presence of the shareholders or their proxies at the location of the Annual General Meeting (virtual Annual General Meeting).</p>	<p>Under Delaware law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the bylaws.</p>
General Meeting	<p>Under the law, extraordinary shareholders' meetings, in addition to the annual shareholders' meetings, may be called either by the Management Board, or the Supervisory Board. Shareholders holding at least 5% of the company's share capital are entitled to request that an extraordinary shareholders' meeting be convened. In the event that the meeting is not then so convened, a competent court may order that the meeting be convened or authorize the shareholders or their representative to convene the meeting themselves.</p>	<p>Under Delaware law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.</p>

Notice of General Meetings

Under applicable European and German law, unless a longer period is otherwise provided for in the articles of association or applies because of registration requirements stipulated in the articles of association, the shareholders must be given at least 30 days' advance notice of the shareholders' meeting. Such notices must at least specify the name of the company, the statutory seat of the company, and the location, date and time of the shareholders' meeting. In addition, the invitation must contain the agenda items as well as the Management Board's and the Supervisory Board's voting proposal for each agenda item and, depending on the circumstances, certain further information.

If all shareholders entitled to attend the shareholders' meeting are present or represented and do not object to the meeting being held, the formalities of calling and holding of a shareholders' meeting do not apply.

Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.

Proxy

A shareholder may designate another person to attend, speak and vote at a shareholders' meeting of the company on such shareholder's behalf by proxy.

With respect to Management Board meetings, a Management Board member may transmit its (written or verbal) vote via another Management Board member.

With respect to Supervisory Board meetings, a Supervisory Board member may participate in voting by issuing a written vote to another Supervisory Board member or any third party entitled to attend the Supervisory Board meeting.

Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

Preemptive Rights	<p>Under the law applicable to European stock corporations governed by German law, existing shareholders have a statutory subscription right for any additional issue of shares or any security convertible into shares pro rata to the nominal value of their respective holdings in the company, unless (i) shareholders representing three-quarters of the registered share capital present at the shareholders' meeting have resolved upon the whole or partial exclusion of the subscription right and (ii) there exists good and objective cause for such exclusion. No separate resolution on the exclusion of subscription rights is required if all shareholders waive their statutory subscription rights.</p>	<p>Under Delaware law, stockholders have no preemptive rights to subscribe to additional issues of stock or to any security convertible into such stock unless, and except to the extent that, such rights are expressly provided for in the certificate of incorporation.</p>
Authority to Allot	<p>Under applicable European and German law, the Management Board may not allot shares, grant rights to subscribe for or to convert any security into shares unless a shareholder resolution to that effect has been passed at the company's shareholders' meeting granting the Management Board with such authority—subject to the approval of the Supervisory Board—in each case in accordance with the provisions of the German Stock Corporation Act.</p>	<p>Under Delaware law, if the corporation's certificate of incorporation so provides, the board of directors has the power to authorize the issuance of stock. It may authorize capital stock to be issued for consideration consisting of cash, any tangible or intangible property or any benefit to the corporation or any combination thereof. It may determine the amount of such consideration by approving a formula. In the absence of actual fraud in the transaction, the judgment of the directors as to the value of such consideration is conclusive.</p>

Liability of Directors and Officers

Under German law, any provision, whether contained in the company's articles of association or any contract or otherwise, that purports to exempt a Management or Supervisory Board member from any liability that would otherwise attach to such board member in connection with any negligence, default, breach of duty or breach of trust in relation to the company is void.

Under German law, members of both the Management Board and members of the Supervisory Board are liable to the company, and in certain cases to third parties or shareholders, for any damage caused to them due to a breach of such member's duty of care. Apart from insolvency or special circumstances, only the company has the right to claim damages from members of either board. The company may waive claims for damages against a negligent Management or Supervisory Board member only after the expiry of three years.

Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director to the corporation and its stockholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or
- any transaction from which the director derives an improper personal benefit.

Voting Rights

Under the relevant European and German law, each share, except for statutory non-voting preferred shares (*nicht stimmberechtigte Vorzugsaktien*), entitles its holder to vote at the shareholders' meeting with, in the case of no-par value shares, each share conferring one vote. While German law does not provide for a minimum attendance quorum for shareholders' meetings, the company's articles of association may so provide. In general, resolutions adopted at a shareholders' meeting may be passed by a simple majority of votes cast, unless a higher majority is required by law or under the company's articles of association.

Delaware law provides that, unless otherwise provided in the certificate of incorporation, each stockholder is entitled to one vote for each share of capital stock held by such stockholder.

Shareholder Vote on Certain Transactions

Under applicable European and German law, certain shareholders' resolutions of fundamental importance require the vote of at least three-quarters of the share capital present or represented in the voting at the time of adoption of the resolution. Resolutions of fundamental importance include, in particular, capital increases with exclusion of subscription rights, capital decreases, the creation of authorized or conditional share capital, the dissolution of a company, a merger into or with another company, split-offs and split-ups, the conclusion of inter-company agreements (*Unternehmensverträge*), in particular domination agreements (*Beherrschungsverträge*) and profit and loss transfer agreements (*Ergebnisabführungsverträge*).

Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires:

- the approval of the board of directors; and
- approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of a corporation entitled to vote on the matter.

Standard of Conduct for Directors

Under applicable European and German law, both Management and Supervisory Board members must conduct their affairs with “the care and diligence of a prudent business man” and act in the best interest of the company. The scope of the fiduciary duties of Management and Supervisory Board members is generally determined by European and German legislation and by the courts.

Statutory and fiduciary duties of members of the Management Board to the company include, among others:

- to act in accordance with the law, the company’s articles of association and the rules of procedure for the Management Board, if any;
- to report to the Supervisory Board on a regular basis as well as on certain important occasions;
- to exercise reasonable care, skill and diligence;
- to maintain a proper accounting system;
- to not compete, directly or indirectly, with the company without permission by the supervisory board; and
- to secure that no further transactions are made in case of insolvency.

Statutory and fiduciary duties of members of the Supervisory Board to the company include, among others:

- to effectively supervise the Management Board’s handling of the company’s affairs;
- to evaluate and issue a resolution on certain transactions which can only be conducted by the Management Board after approval of the Supervisory Board;
- to approve the company’s financial statements;
- to appoint the Management Board members and to represent the company in transactions between the company and members of the Management Board; and
- to approve service contracts between individual members of the Management Board and the company.

Delaware law does not contain specific provisions setting forth the standard of conduct of a director. The scope of the fiduciary duties of directors is generally determined by the courts of the State of Delaware. In general, directors have a duty to act without self-interest, on a well-informed basis and in a manner they reasonably believe to be in the best interest of the stockholders.

Directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its stockholders. The duty of care generally requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. In general, but subject to certain exceptions, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation.

In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the stockholders.

Stockholder Actions

Under German law, generally, the company, rather than its shareholders, is the proper claimant in an action with respect to a wrong committed against the company, or in cases where there is an irregularity in the company's internal management or supervision. Therefore, such claims may only be raised by the company represented by its Management Board, or, in the case of a wrong committed by a member of the Management Board, by the Supervisory Board.

Additionally, pursuant to German case law, the Supervisory Board is obliged to pursue the company's claims against the Management Board, unless the interest of the company keeps them from doing so.

The Management Board, or, if a claim is against a member of the Management Board, the Supervisory Board, is obliged to pursue the company's claims against the designated individuals if so resolved by a simple majority of votes cast during a shareholders' meeting. With a simple majority of votes, shareholders can request that a representative pursues the claim on behalf of the company.

If the company is unable to fulfill its third-party obligations, the company's creditors may pursue the company's damage claims against members of the Management Board for certain wrongdoings.

Under certain circumstances, shareholders can bring forward damage claims of the company against its management on their own behalf. In order to bring forward such a claim one shareholder alone or together with other shareholders needs to hold at least one percent of the company's share capital or a participation of €100,000 in the share capital. Additionally, the claimant(s) need(s) to pass through special claim approval procedures.

Under Delaware law, a stockholder may initiate a derivative action to enforce a right of a corporation if the corporation fails to enforce the right itself. The complaint must:

- state that the plaintiff was a stockholder at the time of the transaction of which the plaintiff complains or that the plaintiff's shares thereafter devolved on the plaintiff by operation of law; and
- either (i) allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action, or (ii) or state the reasons for not making the effort.

Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.

Foreign Private Issuer Exemptions

As a “foreign private issuer,” as defined by the SEC, although we are permitted to follow certain corporate governance practices of the Federal Republic of Germany, instead of those otherwise required under the rules of the Nasdaq Stock Market LLC, or Nasdaq, for domestic issuers, we follow the Nasdaq corporate governance rules applicable to foreign private issuers. While we voluntarily follow most Nasdaq corporate governance rules, we intend to take advantage of the following limited exemptions:

- exemption from filing quarterly reports on Form 10-Q and providing current reports on Form 8-K disclosing significant events within four days of their occurrence (however, we intend to furnish quarterly financial information under cover of Form 6-K);
- exemption from compliance with Regulation FD, which generally requires that when a company intentionally discloses material non-public information, it do so through a public disclosure that is broadly available to all members of the public at the same time. However, we do furnish quarterly financial information and other information on a more frequent basis under cover of Form 6-K, and intend to continue doing so. Moreover, we comply with other securities laws, such as rule 10b-5 (rule targeting securities fraud), among others;
- exemption from Section 16 rules regarding sales of ordinary shares by insiders, which will provide less data in this regard than the data provided to shareholders of U.S. companies that are subject to the Exchange Act; and
- exemption from the Nasdaq rules applicable to domestic issuers requiring disclosure within four business days of any determination to grant a waiver of the code of business conduct and ethics to directors and officers. Although we will require board approval of any such waiver, we may choose not to disclose the waiver in the manner set forth in the Nasdaq rules, as permitted by the foreign private issuer exemption.

Furthermore, Nasdaq Rule 5615(a)(3) provides that, as a foreign private issuer, we may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and Rule 5250(d), provided that we nevertheless comply with Nasdaq’s Notification of Noncompliance requirement (Rule 5625) and the Voting Rights requirement (Rule 5640) and that we have an audit committee that satisfies Rule 5605(c)(3), consisting of committee members that meet the independence requirements of Rule 5605(c)(2)(A)(ii). Although we are permitted to follow certain corporate governance rules that conform to German requirements in lieu of many of the Nasdaq corporate governance rules, we comply with the Nasdaq corporate governance rules applicable to foreign private issuers. We may utilize these exemptions for as long as we continue to qualify as a foreign private issuer.

Item 16H. Mine Safety Disclosure

Not applicable.

Item 16I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Item 16J. Insider Trading Policies

Not applicable.

Item 16K. Cybersecurity

Risk Management and Strategy

Our cybersecurity approach strives to adequately protect our information, systems, assets, physical locations, and people. From a business perspective, this means protecting key information assets and complying with applicable international and national privacy laws, information security policies and contractual obligations. Our Information Security Policy, adopted in 2023, defines our information security management objectives and principles, and our Data Privacy Policy, effective since 2021, provides for a consistent level of company-wide data privacy and data protection. In addition, our Information Classification Policy, introduced internally during the year ended December 31, 2023, provides a system for classifying and protecting our physical and digital assets. These policies are applicable to BioNTech SE and its affiliates, including all Supervisory Board and Management Board members, as well as all other officers and employees,

and are part of our overall Information Security Management System (ISMS) that is currently being operationalized as part of the preparation for the ISO 27001 certification. Our processes for assessing, identifying, and managing material risks from cybersecurity threats are integrated into our overall enterprise risk management system, which was developed with input from internal and external experts.

We collaborated with external experts through early 2023 to develop a Security Transformation Program. Our main cyber and information security objectives are to maintain information confidentiality, integrity, and availability.

Since the year ended December 31, 2022, we have been using a data privacy system to assess the data privacy risks for each system in place. It also provides for proper data mapping, up-to-date recordkeeping on processing, data transfer impact assessments, and vendor data management. During the year ended December 31, 2023, we established a dedicated, standardized process to report data breaches. This process is intended to ensure that we are promptly notified of data breaches so that we can inform the people affected. The dialogue between our Data Privacy department and other functions also supports the early detection of data privacy risks. In addition, as part of the ISMS, employees are required to communicate any potential improvements or discrepancies as the system evolves.

We also regularly streamline information security processes and measures in our business operations and work to ensure that newly introduced applications adhere to the “secure by design” principle. We also work to improve our cyber and information security management system on an ongoing basis to address evolving risks and regulatory requirements according to the relevant certification processes.

To achieve and preserve information security, we strive for the orderly planning, implementation, control, and optimization of all activities required for the protection of data privacy and the detection, response and recovery of data privacy risks. We rely on applicable international standards as guidance, including ISO/IEC 27001, which is internally recognized and serves as the framework for the Company’s ISMS. We aim to prepare our organization for relevant certifications in 2024 to aim for certification in 2025. We will initially seek certifications for our main manufacturing facility and an R&D site in addition to the cybersecurity organization.

We take responsibility for the transparent communication and proper processing of personal data. This includes the storage, access, retention, and security of all personal data when engaging with patients, employees, customers, business partners, and vendors. We communicate our practices in a data privacy statement on our corporate website. We require the third parties with which we contract to adhere to contractual privacy and security provisions, and we request specific information from major vendors about their practices in protecting data privacy.

When processing personal data, we are responsible for ensuring that we comply with applicable data protection laws. These include the European Union’s General Data Protection Regulation (GDPR), the German Commercial Code (HGB), the German Federal Data Protection Act (BDSG), the German IT Security Act 2.0 (IT-SiG 2.0), the German Federal Office for Information Security Act (BSIG), and other privacy and data security laws in the jurisdictions where we operate. In April 2023, we were designated as a part of Germany’s critical infrastructure (KRITIS) under the BSIG, which has resulted in heightened reporting and verification obligations. We are in the process of implementing a global data privacy framework that sets out the requirements and standards applicable to processing personal data. The framework is being designed to foster compliance with the applicable regulations and sets minimum standards for the Company. As part of our global strategy, privacy-related documents, such as informed consent forms for clinical trials, are being standardized company-wide. The forms facilitate the user-friendly implementation of the standards we have established and provide transparency on how and why we process personal data.

Creating and maintaining mature levels of cyber and information security within BioNTech, in the supply chain, and in close collaboration with partners requires the commitment of all employees. In 2023, we began deploying Data Privacy Regional Leads, supported at a team level by Data Privacy Liaisons. At the end of 2023, we were continuing to recruit for these positions for further support. Members of relevant teams, such as IT and Clinical Operations, are selected to work closely with the Data Privacy team to ensure compliance with the relevant data privacy regulations.

After implementing the key milestones of the Security Transformation Roadmap over the past two years, our focus in 2023 was on:

- improving the operational excellence of cybersecurity services;
- identifying further automatization options (e.g., introducing self-services);
- optimizing the ISMS framework based on an internal audit, independent feedback and recommendations, and cooperation with external experts;

- establishing mandatory cyber and information security training for all employees at least annually, including phishing simulations at least twice a year;
- reducing the internal and external attack surface through regular vulnerability scanning, penetration testing, and maintaining IT supplier and software confidentiality; and
- establishing a security reporting dashboard to provide executive stakeholders with transparency into relevant activities.

In 2023, there were no substantiated complaints concerning material data breaches, including leaks, thefts, or losses of personal data such as patient or customer data. Contracts and confidentiality agreements with clinical trial sites were compliant with relevant regulations. We do not believe that any cybersecurity threats in 2023, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition. For a discussion of cybersecurity and data privacy-related risks and uncertainties, see Item 3.D, “Risk Factors,” of this Annual Report on Form 20-F.

Governance

We take a centralized approach to managing cyber and information security to facilitate a consistency and compliance across entities and locations.

Our Chief Operating Officer (COO) and Management Board member, Sierk Poetting, is responsible for assessing and managing our material risks from cybersecurity threats. His ambit includes reviewing our information security capabilities, reporting data privacy issues to the Management Board, and supporting our Information Security Organization (ISO) in obtaining the resources it needs. The COO’s extensive experience in risk management, operations and corporate governance, with over 11 years of experience in the pharmaceutical industry in particular, are critical to the management of cyber and information security at the Company. The ISO oversees all roles and responsibilities associated with the ISMS. Representatives from the ISO provide monthly updates to the Management Board and annual updates to the Supervisory Board.

The COO is supported by the Chief Information Security Officer (CISO), who leads the ISO and is accountable for security strategy, operations, and policy development and implementation. Our CISO, Raimond Jähn, was the department lead of our IT security team starting in 2016, has led the cyber and information security transformation program towards a new operating model since 2021, and was formally designated as CISO by the COO in 2023. Our Head of Cyber and Information Security, Data Protection Officer, and Head of Global Security and Protection each bring in additional expertise.

Our overarching strategy was developed in 2021 by the COO and CISO in alignment with the Data Protection Officer and Head of Global Security and Protection, and is regularly updated.

Data privacy matters fall under the purview of our Chief Legal Officer (CLO) and Management Board member, James Ryan, who is supported by our Senior Director, Data Privacy, Dr. Ryan’s qualifications include close to twenty years of expertise in legal and intellectual property matters, both within the pharmaceutical industry as well as as an outside counsel with a focus on strategic life sciences transactions. Together with his deep familiarity with the Company’s history, operations, and processes, James Ryan is uniquely positioned to advise on data privacy matters.

For additional information on Sierk Poetting’s and James Ryan’s experience, see Item 6.A, “Directors and Senior Management.”

PART III

Item 17. Financial Statements

See Item 18.

Item 18. Financial Statements

The financial statements are filed as part of this Annual Report beginning on page F-1.

Item 19. Exhibits

Exhibit Number	Description
1.1	Articles of Association of the Registrant (incorporated herein by reference to Exhibit 4.1 to the Registrant’s Registration Statement on Form S-8 (File No. 333-277105), filed with the SEC on February 15, 2024)
2.1	Form of Specimen American Depositary Receipt (included in Exhibit 2.3)
2.2	Registrant’s Specimen Certificate for Ordinary Shares (incorporated herein by reference to Exhibit 4.2 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
2.3	Form of Deposit Agreement among the Registrant, the depositary and holders and beneficial owners of the American Depositary Shares (incorporated herein by reference to Exhibit 1 to the Registration Statement on Form F-6 (File No. 333-233898), filed with the SEC on September 23, 2019)
2.4*	Description of Securities of the Registrant
4.1†	Master Agreement for Research Services by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, Eufets GmbH, JPT Peptide Technologies GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, dated January 1, 2015 (incorporated herein by reference to Exhibit 10.1 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.2†	Confirmation Letter by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH dated September 15, 2016 (incorporated herein by reference to Exhibit 10.2 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.3†	Supplementary Agreement for [***] Developments to the Master Agreement for Research Services by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, BioNTech Innovative Manufacturing Services GmbH (f/k/a Eufets GmbH), JPT Peptide Technologies GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, dated November 28, 2017 (incorporated herein by reference to Exhibit 10.3 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.4†	License Agreement by and among the Registrant, TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, Johannes Gutenberg-Universität Mainz, Universitätsmedizin der Johannes Gutenberg-Universität and Ganymed Pharmaceuticals AG, dated January 1, 2015 (incorporated herein by reference to Exhibit 10.4 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.5†	Framework Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, BioNTech Innovative Manufacturing Services GmbH, JPT Peptide Technologies GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, dated August 29, 2019 (incorporated herein by reference to Exhibit 10.5 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)

Exhibit Number	Description
4.6†	Amended Patent License Agreement by and among the Registrant, the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College and Uniwersytet Warszawski, dated May 12, 2015 (incorporated herein by reference to Exhibit 10.6 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.7†	Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, dated September 20, 2016 (incorporated herein by reference to Exhibit 10.14 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.8†	First Amendment to the Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, dated June 1, 2018 (incorporated herein by reference to Exhibit 4.15 to the Registrant’s Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 31, 2020)
4.9†	Second Amendment to the Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, dated December 6, 2019 (incorporated herein by reference to Exhibit 4.16 to the Registrant’s Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 31, 2020)
4.10	Joinder and Third Amendment to the Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Manufacturing GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, effective as of October 1, 2020 (incorporated herein by reference to Exhibit 4.16 to the Registrant’s Annual Report on Form 20-F (File No. 001-39081) filed with the SEC on March 30, 2022)
4.11†	Fourth Amendment to the Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Manufacturing GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, effective as of October 26, 2020 (incorporated herein by reference to Exhibit 4.17 to the Registrant’s Annual Report on Form 20-F (File No. 001-39081) filed with the SEC on March 30, 2022)
4.12†	Patent Sublicense Agreement by and between CellScript, LLC and BioNTech RNA Pharmaceuticals GmbH, dated July 14, 2017 (incorporated herein by reference to Exhibit 10.15 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.13†	Second Amendment to Patent Sublicense Agreement by and between CellScript, LLC and BioNTech RNA Pharmaceuticals GmbH, effective as of August 1, 2020 (incorporated herein by reference to Exhibit 4.19 to the Registrant’s Annual Report on Form 20-F (File No. 001-39081) filed with the SEC on March 30, 2022)
4.14†	Patent Sublicense Agreement by and between mRNA RiboTherapeutics, Inc. and BioNTech RNA Pharmaceuticals GmbH, dated July 14, 2017 (incorporated herein by reference to Exhibit 10.16 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.15†	Second Amendment to Patent Sublicense Agreement by and between mRNA RiboTherapeutics, Inc. and BioNTech RNA Pharmaceuticals GmbH, effective as of August 1, 2020 (incorporated herein by reference to Exhibit 4.21 to the Registrant’s Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 30, 2022)
4.16†	Research Collaboration and License Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH and Pfizer, Inc., dated July 20, 2018 (incorporated herein by reference to Exhibit 10.18 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.17†	Collaboration and License Agreement by and between the Trustees of the University of Pennsylvania and BioNTech RNA Pharmaceuticals GmbH, dated October 9, 2018 (incorporated herein by reference to Exhibit 10.19 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)

Exhibit Number	Description
4.18†	Lease Agreement by and among the Registrant and Wolfram Richter, dated August 17, 2011 (incorporated herein by reference to Exhibit 10.25 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.19†	Amendment No. 1 to Lease Agreement by and among the Registrant and Wolfram Richter, dated February 17, 2012 (incorporated herein by reference to Exhibit 10.26 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.20†	Amendment No. 2 to Lease Agreement by and among the Registrant and Wolfram Richter, dated February 1, 2013 (incorporated herein by reference to Exhibit 10.27 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.21†	Amendment No. 3 to Lease Agreement by and among the Registrant and Wolfram Richter, dated March 6, 2013 (incorporated herein by reference to Exhibit 10.28 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.22†	Amendment No. 4 to Lease Agreement by and among the Registrant and Wolfram Richter, dated December 10, 2013 (incorporated herein by reference to Exhibit 10.29 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.23†	Amendment No. 5 to Lease Agreement by and among the Registrant and Wolfram Richter, dated March 29, 2016 (incorporated herein by reference to Exhibit 10.30 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.24†	Amendment No. 6 to Lease Agreement by and among the Registrant and Wolfram Richter, dated October 6, 2017 (incorporated herein by reference to Exhibit 10.31 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.25†	Lease Agreement by and among the Registrant and Wista-Management GmbH, dated April 12, 2005 (incorporated herein by reference to Exhibit 10.32 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.26†	Amendment to Lease Agreement by and among the Registrant and Wista-Management GmbH, dated December 27, 2018 (incorporated herein by reference to Exhibit 10.33 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.27†	Amendment to Lease Agreement by and among the Registrant and Wista-Management GmbH, dated October 24, 2019 (incorporated herein by reference to Exhibit 4.35 to the Registrant’s Annual Report on Form 20-F (File No. 001-39081) filed with the SEC on March 31, 2020)
4.28†	Amendment to Lease Agreement by and among the Registrant and Wista-Management GmbH, dated June 1, 2020 (incorporated herein by reference to Exhibit 10.38 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233970), filed with the SEC on July 21, 2020)
4.29†	Amended and Restated Collaboration Agreement by and between the Registrant and Pfizer Inc., dated March 17, 2020 (incorporated herein by reference to Exhibit 4.44 to the Registrant’s Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 30, 2021)
4.30†	Advance Purchase Agreement by and among BioNTech Manufacturing GmbH, Pfizer Inc., and the European Commission, dated November 20, 2020 (incorporated herein by reference to Exhibit 4.51 to the Registrant’s Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 30, 2021)
4.31†	Purchase Agreement by and among BioNTech Manufacturing GmbH, Pfizer Inc., and the European Commission, dated February 17, 2021 (incorporated herein by reference to Exhibit 4.52 to the Registrant’s Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 30, 2021)
4.32†	Lease for Buildings H028 and H30 by and between the Pharmaserv GmbH and Novartis Manufacturing GmbH (incorporated herein by reference to Exhibit 4.53 to the Registrant’s Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 30, 2021)

Exhibit Number	Description
4.33†	<u>Lease Agreement by and between the Registrant, as successor-in-interest to Kite Pharma, Inc., and Tech Park 270 III, LLC, dated as of December 1, 2017 (incorporated herein by reference to Exhibit 4.34 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)</u>
4.34†	<u>Amendment No. 3 to Lease Agreement by and between the Registrant, as successor-in-interest to Kite Pharma, Inc., and Tech Park 270 III, LLC, dated as of July 24, 2018 (incorporated herein by reference to Exhibit 4.35 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)</u>
4.35†	<u>Amendment No. 4 to Lease Agreement by and between the Registrant, as successor-in-interest to Kite Pharma, Inc., and Tech Park 270 III, LLC, dated as of May 23, 2019 (incorporated herein by reference to Exhibit 4.36 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)</u>
4.36†	<u>License Agreement by and between the Registrant and Acuitas Therapeutics, Inc., dated as of April 7, 2020 (incorporated herein by reference to Exhibit 4.37 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)</u>
4.37†	<u>Advanced Purchase Agreement by and among the Registrant, Pfizer Inc. and European Commission, dated as of May 20, 2021 (incorporated herein by reference to Exhibit 4.38 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)</u>
4.38†	<u>Transfer of Source Code for MyMUT Software Versions by and between the Registrant and TRON gmbH, dated as of May 5, 2021 (incorporated herein by reference to Exhibit 4.39 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)</u>
4.39†	<u>Amendment No. 6 to Lease Agreement by and between the Registrant and Tech Park 270, LLC, dated as of August 2, 2021 (incorporated herein by reference to Exhibit 4.40 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)</u>
4.40†	<u>Side Letter No. 5 to License and Collaboration Agreement by and between Registrant and Genmab A/S, dated August 12, 2021 (incorporated herein by reference to Exhibit 4.41 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)</u>
4.41†	<u>Amendment No. 1 to Collaboration and License Agreement by and between the Registrant and the Trustees of the University of Pennsylvania, dated as of September 8, 2021 (incorporated herein by reference to Exhibit 4.42 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)</u>
4.42†	<u>Transfer of Source Code MyMUT Software Versions by and between the Registrant and TRON gmbH, dated as of September 10, 2021 (incorporated herein by reference to Exhibit 4.43 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)</u>
4.43†	<u>Amendment No. 2 to Collaboration and License Agreement by and between the Registrant and the Trustees of the University of Pennsylvania, dated as of December 22, 2021 (incorporated herein by reference to Exhibit 4.44 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)</u>
4.44†	<u>Lease for Areas and Rooms in Building 536 and 537 by and between the Pharmaserv GmbH and Novartis Manufacturing GmbH, dated as of January 19, 2022 (incorporated herein by reference to Exhibit 4.45 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)</u>
4.45†	<u>Amended and Restated License and Collaboration Agreement, by and between BioNTech SE and Genmab A/S, entered into July 18, 2022, effective as of May 19, 2015 (incorporated herein by reference to Exhibit 4.46 to the Registrant's Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)</u>

Exhibit Number	Description
4.46†	Real Estate Purchase Contract with Conveyance Together with Inventory Purchase Contract by and between Santo Service GmbH, BioNTech Real Estate An der Goldgrube 12 GmbH & Co. KG and BioNTech Manufacturing GmbH, dated as of December 12, 2022 (incorporated herein by reference to Exhibit 4.47 to the Registrant’s Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on March 27, 2023)
4.47*†	Deed of Amendment of Agreement related to the Sale and Purchase of Certain Shares of the Issued Share Capital of InstaDeep Ltd by and among the Registrant, InstaDeep Ltd and the Sellers set forth therein, dated as of July 31, 2023
4.48*†	License and Collaboration Agreement, by and between the Registrant and OncoC4, Inc., dated as of March 17, 2023
4.49*†	Amendment No. 1 to the License and Collaboration Agreement, by and between the Registrant and OncoC4, Inc., dated as of February 14, 2024
4.50*†	License and Collaboration Agreement (HER2), by and between the Registrant and Duality Biologics (Suzhou) Co. Ltd., dated as of March 16, 2023
4.51*†	License and Collaboration Agreement (B7H3), by and between the Registrant and Duality Biologics (Suzhou) Co. Ltd., dated as of March 31, 2023
4.52*†	License and Collaboration Agreement (TROP2), by and between the Registrant and Duality Biologics (Suzhou) Co. Ltd., dated as of August 4, 2023
4.53*†	Collaboration, License and Option Agreement, by and between the Registrant and Biotheus Inc., dated as of October 26, 2023
4.54*†	License and Option Agreement, by and among Autolus Limited, Autolus Holdings (UK) Limited and the Registrant, dated as of February 6, 2024
8*	List of Subsidiaries of the Registrant
12.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.1*	Consent of EY GmbH & Co. KG Wirtschaftsprüfungsgesellschaft
97*	Compensation Clawback Policy
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

† Certain information has been excluded from the exhibit because it is both (i) not material and (ii) the type of information that the Registrant treats as private or confidential.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Supervisory Boards of BioNTech SE

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of BioNTech SE (the Company) as of December 31, 2023 and 2022, the related consolidated statements of profit or loss, comprehensive income, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standard Board.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission "(2013 framework)," and our report dated March 20, 2024, expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of Intangible assets acquired within Business Combination of InstaDeep Ltd.

Description of the Matter

As described in more detail in Note 5 to the consolidated financial statements, in July 2023 the Company completed its acquisition of InstaDeep Ltd. for a total purchase price of €517.5 million. As a result of the acquisition, the Company acquired Intangible assets including the DeepChain technology.

Auditing the valuation of the acquired intangible assets was complex due to the significant estimation uncertainty in determining the fair value of the intangible assets. The fair value determination is based on a discounted cash flow model using certain assumptions containing high subjectivity, such as future cost savings that are based on number of candidate discoveries and probability of technical success to which royalty rates are applied. These significant assumptions are forward-looking and could be affected by future economic and market conditions.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of controls over the Company's process for evaluating the intangible assets acquired within the Business Combination. This included testing controls over management's review of assumptions and inputs used to calculate the valuation of the acquired intangible assets.

Our audit procedures included, among others, evaluating management's approach to determine expected number of candidate discoveries by comparing it to historical data. We tested the probability of technical success by comparing the rates used to past results of similar products in development within the industry. For royalty rates applied we benchmarked those against comparable license agreements.

Our procedures included sensitivity analysis of the significant assumptions to evaluate the change in the fair value of the acquired intangible assets resulting from changing the assumptions.

Further, with the assistance of our valuation specialists, we assessed the appropriateness of the valuation method used and the discount rate utilized by comparing to underlying source information.

We evaluated the adequacy of the Company's disclosures in relation to these matters.

Revenue recognition from collaboration partner's COVID-19 vaccine sales

Description of the Matter

As described in more detail in Note 6 to the consolidated financial statements, the Company recognizes revenues associated with COVID-19 vaccine sales in a total amount of €3.8 billion. This includes €3.0 billion from the Company's share of its collaboration partner's gross profit.

The Company is contractually eligible to receive a share of the collaboration partner's gross profit from vaccine sales in the collaboration partner's territories. Such gross profit share is recognized as collaboration revenue. In order to determine the gross profit share, the Company uses certain information from the collaboration partner, including vaccine sales outside of the United States and associated production costs, some of which is based on preliminary data shared by the partner and might differ once final data is available.

Auditing revenue recognition specific to the gross profit share was complex due to the significant estimation uncertainty in inputs to the calculation. Specifically, the collaboration partner's vaccine sales outside of the United States and associated manufacturing and shipping costs are partially estimated for the last month in the period based on historical information and could change based on the actual vaccine sales and costs incurred.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of the Company's controls related to revenue recognition from the collaboration partner's vaccine sales outside of the United States. For example, we tested controls over management's review of the significant assumptions used to determine the gross profit share the Company is eligible to receive.

Our audit procedures included, among others, reading the contract with the collaboration partner to understand key terms and obtaining an understanding of management's methodology and assumptions used to calculate the gross profit share. We performed a hindsight analysis to assess management's accuracy in estimating the collaboration partner's vaccine sales outside of the United States and manufacturing and shipping costs. We obtained a confirmation directly from the collaboration partner regarding vaccine sales and cost inputs used to estimate the profit share. We performed a sensitivity analysis of the significant assumptions to evaluate the change in the gross profit share resulting from changing the assumptions, as well as an analysis of previous estimation compared to the actual payments obtained to date. We tested the completeness and accuracy of the Company's gross profit share calculation. We evaluated the Company's related disclosures in the consolidated financial statements.

Claims and legal contingencies

Description of the Matter

As described in more detail in Note 18 to the consolidated financial statements, the Company is involved in various claims and litigation specifically related to patent infringements and product liability matters. The Company, assisted by their internal and external legal counsel, assesses the need to record a provision or disclose a contingency on a case-by-case basis considering the underlying facts of each matter. The Company discloses contingent liabilities in circumstances where a cash outflow is probable, but management is unable to make a reasonable estimate of the expected financial effect that will result from ultimate resolution of the proceeding, or a cash outflow is reasonably possible. A provision is recorded when a cash outflow is deemed probable and reasonably estimable.

Auditing management's determination of whether a loss of such patent or product liability matters is probable and reasonably estimable, reasonably possible or remote, and the related disclosures, is highly subjective and requires significant judgement.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of the Company's controls in assessing the completeness, valuation, presentation and disclosures with respect to such claims and legal proceedings. For example, this included testing controls related to the Company's process for identification, recognition, measurement and disclosure of claims and legal contingencies.

We assessed the completeness of the claims and legal proceedings subject to evaluation by the Company and assessed their determination of the probability of their outcomes through review of presentations for board meetings and inspection of responses to inquiry letters received from both internal and external legal counsels. Further, we held discussions with internal and external legal counsels to confirm our understanding of the allegations, reviewed legal expenses incurred, evaluated resolutions of claims already concluded against management's assessment and obtained written representations from executives of the Company confirming the completeness and accuracy of the information provided.

We evaluated the adequacy of the Company's disclosures in relation to these matters.

/s/ EY GmbH & Co. KG Wirtschaftsprüfungsgesellschaft

We have served as the Company's auditor since 2018

Cologne, Germany

March 20, 2024

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Supervisory Board of BioNTech SE

Opinion on Internal Control Over Financial Reporting

We have audited BioNTech SE's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission "(2013 framework)," (the COSO criteria). In our opinion, BioNTech SE (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

As indicated in the accompanying Management's Annual Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of InstaDeep Ltd., which is included in the 2023 consolidated financial statements of the Company and constituted 2.2% of total assets, respectively, as of December 31, 2023 and 0.1% of revenues and constituted €31.7 million of net loss included within the €930.3 million total profit for the year then ended. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of InstaDeep Ltd.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated statements of financial position of the Company as of December 31, 2023 and 2022, the related consolidated statements of profit or loss, comprehensive income, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2023, and the related notes and our report dated March 20, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ EY GmbH & Co. KG Wirtschaftsprüfungsgesellschaft
Cologne, Germany
March 20, 2024

_Consolidated Statements of Profit or Loss

<i>(in millions €, except per share data)</i>	Note	Years ended December 31,		
		2023	2022	2021
Revenues				
Commercial revenues	6	3,815.5	17,194.6	18,874.0
Research & development revenues	6	3.5	116.0	102.7
Total revenues		3,819.0	17,310.6	18,976.7
Cost of sales	7.1	(599.8)	(2,995.0)	(2,911.5)
Research and development expenses	7.1	(1,783.1)	(1,537.0)	(949.2)
Sales and marketing expenses	7.1	(62.7)	(59.5)	(50.4)
General and administrative expenses ⁽¹⁾	7.1	(495.0)	(481.7)	(276.8)
Other operating expenses ⁽¹⁾	7.2	(293.0)	(410.0)	(103.4)
Other operating income	7.3	105.0	815.3	598.4
Operating income		690.4	12,642.7	15,283.8
Finance income	7.4	519.6	330.3	67.7
Finance expenses	7.5	(23.9)	(18.9)	(305.1)
Profit before tax		1,186.1	12,954.1	15,046.4
Income taxes	8	(255.8)	(3,519.7)	(4,753.9)
Profit for the period		930.3	9,434.4	10,292.5
Earnings per share				
Basic earnings for the period per share	9	3.87	38.78	42.18
Diluted earnings for the period per share	9	3.83	37.77	39.63

⁽¹⁾ Adjustments to prior-year figures due to change in functional allocation of general and administrative expenses and other operating expenses (see Note 7.2).

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Comprehensive Income

<i>(in millions €)</i>	Note	Years ended December 31,		
		2023	2022	2021
Profit for the period		930.3	9,434.4	10,292.5
Other comprehensive income				
<i>Other comprehensive income that may be reclassified to profit or loss in subsequent periods, net of tax</i>				
Exchange differences on translation of foreign operations		(19.8)	11.2	8.4
Net other comprehensive income / (loss) that may be reclassified to profit or loss in subsequent periods		(19.8)	11.2	8.4
<i>Other comprehensive loss that will not be reclassified to profit or loss in subsequent periods, net of tax</i>				
Net gain on equity instruments designated at fair value through other comprehensive income		3.7	10.5	—
Remeasurement gain on defined benefit plans		0.3	0.6	0.3
Net other comprehensive income that will not be reclassified to profit or loss in subsequent periods		4.0	11.1	0.3
Other comprehensive income / (loss) for the period, net of tax		(15.8)	22.3	8.7
Comprehensive income for the period, net of tax		914.5	9,456.7	10,301.2

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Financial Position

<i>(in millions €)</i>		December 31, 2023	December 31, 2022
Assets	Note		
Non-current assets			
Goodwill	10	362.5	61.2
Other intangible assets	10	804.1	158.5
Property, plant and equipment	11	757.2	609.2
Right-of-use assets	20	214.4	211.9
Other financial assets	12	1,176.1	80.2
Other non-financial assets	14	83.4	6.5
Deferred tax assets	8	81.3	229.6
Total non-current assets		3,479.0	1,357.1
Current assets			
Inventories	13	357.7	439.6
Trade and other receivables	12	2,155.7	7,145.6
Contract assets	6	4.9	—
Other financial assets	12	4,885.3	189.4
Other non-financial assets	14	280.9	271.9
Income tax assets	8	179.1	0.4
Cash and cash equivalents	12	11,663.7	13,875.1
Total current assets		19,527.3	21,922.0
Total assets		23,006.3	23,279.1
Equity and liabilities			
Equity			
Share capital	15	248.6	248.6
Capital reserve	15	1,229.4	1,828.2
Treasury shares	15	(10.8)	(5.3)
Retained earnings		19,763.3	18,833.0
Other reserves	16	(984.6)	(848.9)
Total equity		20,245.9	20,055.6
Non-current liabilities			
Lease liabilities, loans and borrowings	12	191.0	176.2
Other financial liabilities	12	38.8	6.1
Income tax liabilities	8	—	10.4
Provisions	17	8.8	8.6
Contract liabilities	6	398.5	48.4
Other non-financial liabilities	19	13.1	17.0
Deferred tax liabilities	8	39.7	6.2
Total non-current liabilities		689.9	272.9
Current liabilities			
Lease liabilities, loans and borrowings	12	28.1	36.0
Trade payables and other payables	12	354.0	204.1
Other financial liabilities	12	415.2	785.1
Refund liabilities	6	—	24.4
Income tax liabilities	8	525.5	595.9
Provisions	17	269.3	367.2
Contract liabilities	6	353.3	77.1
Other non-financial liabilities	19	125.1	860.8
Total current liabilities		2,070.5	2,950.6
Total liabilities		2,760.4	3,223.5
Total equity and liabilities		23,006.3	23,279.1

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Changes in Stockholders' Equity

<i>(in millions €)</i>	Note	Equity attributable to equity holders of the parent					Total equity
		Share capital	Capital reserve	Treasury shares	Retained earnings	Other reserves	
As of January 1, 2021		246.3	1,514.5	(4.8)	(409.6)	25.4	1,371.8
Profit for the period		—	—	—	10,292.5	—	10,292.5
Other comprehensive income		—	—	—	—	8.7	8.7
Total comprehensive income		—	—	—	10,292.5	8.7	10,301.2
Issuance of treasury shares	15	—	162.6	1.0	—	—	163.6
Transaction costs		—	(2.7)	—	—	—	(2.7)
Share-based payments	16	—	—	—	—	59.8	59.8
As of December 31, 2021		246.3	1,674.4	(3.8)	9,882.9	93.9	11,893.7
Profit for the period		—	—	—	9,434.4	—	9,434.4
Other comprehensive income		—	—	—	—	22.3	22.3
Total comprehensive income		—	—	—	9,434.4	22.3	9,456.7
Issuance of share capital	15	0.5	67.1	—	—	—	67.6
Redemption of convertible note	12	1.8	233.2	—	—	—	235.0
Share repurchase program	15	—	(979.5)	(6.9)	—	—	(986.4)
Transaction costs		—	(0.1)	—	—	—	(0.1)
Dividends	15	—	—	—	(484.3)	—	(484.3)
Share-based payments	16	—	833.1	5.4	—	(1,519.8)	(681.3)
Deferred taxes	8	—	—	—	—	554.7	554.7
As of December 31, 2022		248.6	1,828.2	(5.3)	18,833.0	(848.9)	20,055.6
Profit for the period		—	—	—	930.3	—	930.3
Other comprehensive loss		—	—	—	—	(15.8)	(15.8)
Total comprehensive profit / (loss)		—	—	—	930.3	(15.8)	914.5
Share repurchase program	15	—	(731.6)	(6.9)	—	—	(738.5)
Share-based payments	16	—	30.2	0.3	—	(15.1)	15.4
Current and deferred taxes	8	—	—	—	—	(104.8)	(104.8)
Treasury shares used for acquisition of business combination	5	—	102.6	1.1	—	—	103.7
As of December 31, 2023		248.6	1,229.4	(10.8)	19,763.3	(984.6)	20,245.9

Consolidated Statements of Cash Flows

<i>(in millions €)</i>	Years ended December 31,		
	2023	2022	2021
Operating activities			
Profit for the period	930.3	9,434.4	10,292.5
Income taxes	255.8	3,519.7	4,753.9
Profit before tax	1,186.1	12,954.1	15,046.4
Adjustments to reconcile profit before tax to net cash flows:			
Depreciation and amortization of property, plant, equipment, intangible assets and right-of-use assets	183.4	123.3	75.2
Share-based payment expenses	51.4	108.6	93.9
Net foreign exchange differences	(298.0)	625.5	(387.5)
Loss on disposal of property, plant and equipment	3.8	0.6	4.6
Finance income excluding foreign exchange differences	(519.6)	(265.3)	(1.5)
Finance expense excluding foreign exchange differences	7.9	18.9	305.2
Movements in government grants	2.4	0.3	(89.0)
Other non-cash income / (loss)	—	—	(2.2)
Net (gain) / loss on derivative instruments at fair value through profit or loss	175.5	(241.0)	57.3
Working capital adjustments:			
Decrease / (increase) in trade and other receivables, contract assets and other assets	5,374.0	4,369.9	(11,808.1)
Decrease / (increase) in inventories	81.9	62.9	(438.4)
Increase in trade payables, other financial liabilities, other liabilities, contract liabilities, refund liabilities and provisions	118.9	85.7	1,516.1
Interest received and realized gains from cash and cash equivalents	258.2	29.3	1.2
Interest paid and realized losses from cash and cash equivalents	(5.4)	(21.5)	(12.2)
Income tax paid	(482.9)	(4,222.1)	(3,457.9)
Share-based payments	(766.2)	(51.8)	(13.4)
Net cash flows from operating activities	5,371.4	13,577.4	889.7
Investing activities			
Purchase of property, plant and equipment	(249.4)	(329.2)	(127.5)
Proceeds from sale of property, plant and equipment	(0.7)	0.6	3.4
Purchase of intangible assets and right-of-use assets	(455.4)	(34.1)	(26.5)
Acquisition of subsidiaries and businesses, net of cash acquired	(336.9)	—	(20.8)
Investment in other financial assets	(7,128.4)	(47.8)	(19.5)
Proceeds from maturity of other financial assets	1,216.3	375.2	(375.2)
Net cash flows used in investing activities	(6,954.5)	(35.3)	(566.1)
Financing activities			
Proceeds from issuance of share capital and treasury shares, net of costs	—	110.5	160.9
Proceeds from loans and borrowings	0.3	0.8	—
Repayment of loans and borrowings	(0.1)	(18.8)	(52.6)
Payments related to lease liabilities	(40.3)	(41.1)	(14.1)
Share repurchase program	(738.5)	(986.4)	—
Dividends	—	(484.3)	—
Net cash flows from / (used in) financing activities	(778.6)	(1,419.3)	94.2
Net increase / (decrease) in cash and cash equivalents	(2,361.7)	12,122.8	417.8
Change in cash and cash equivalents resulting from exchange rate differences	(14.5)	60.1	64.7
Change in cash and cash equivalents resulting from other valuation effects	164.8	(0.5)	—
Cash and cash equivalents at the beginning of the period	13,875.1	1,692.7	1,210.2
Cash and cash equivalents as of December 31	11,663.7	13,875.1	1,692.7

The accompanying notes form an integral part of these consolidated financial statements.

Notes to the Consolidated Financial Statements

1 Corporate Information

BioNTech SE is a limited company incorporated and domiciled in Germany. American Depositary Shares (ADS) representing BioNTech SE's ordinary shares have been publicly traded on the Nasdaq Global Select Market since October 10, 2019. The registered office is located in Mainz, Germany (An der Goldgrube 12, 55131 Mainz). BioNTech SE is registered in the commercial register B of the Mainz Local Court under the number HRB 48720. The accompanying consolidated financial statements, which were prepared in accordance with International Financial Reporting Standards (IFRS), present the financial position and the results of operations of BioNTech SE and its subsidiaries, hereinafter also referred to as "BioNTech," the "Group," "we" or "us."

Our consolidated financial statements for the year ended December 31, 2023, were authorized for issue in accordance with a resolution of the Supervisory Board on March 19, 2024.

2 Significant Accounting Policies

2.1 Basis of Preparation

General

The consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

We prepare and publish our consolidated financial statements in Euros and round numbers to thousands or millions of Euros, respectively. Accordingly, numerical figures shown as totals in some tables may not be exact arithmetic aggregations of the figures that preceded them and figures presented in the explanatory notes may not add up to the rounded arithmetic aggregations. Rounding applied may differ from rounding published in different units in the previous years.

Segment Information

Decisions with respect to business operations and resource allocations are made by our Management Board, as the chief operating decision maker (CODM) based on BioNTech as a whole. Accordingly, we operate and make decisions as a single operating segment, which is also our reporting segment.

2.2 Basis of Consolidation

The consolidated financial statements comprise the financial statements of BioNTech SE and its controlled investees (subsidiaries).

The Group controls an investee if, and only if, the Group has

- power over the investee (*i.e.*, existing rights that give it the current ability to direct the relevant activities of the investee);
- exposure, or rights, to variable returns from its involvement with the investee; and
- the ability to use its power over the investee to affect its returns.

Generally, there is a presumption that a majority of voting rights results in control.

Whether an investee is controlled is re-assessed if facts and circumstances indicate that there are changes to one or more of the three elements of control. Consolidation of a subsidiary begins when control is obtained over the subsidiary and ceases when control over the subsidiary is lost.

The profit / (loss) and each component of other comprehensive income / (loss) for the period are attributed to the equity holders of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. When necessary, adjustments are made to the consolidated financial statements of subsidiaries to bring their accounting policies in line with the Group's accounting policies. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated on consolidation.

A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If control over a subsidiary is lost, the related assets (including goodwill), liabilities, non-controlling interests and other components of equity are derecognized, while any resultant gain or loss is recognized in the consolidated statements of profit or loss. Any investment retained is recognized at fair value.

2.3 Summary of Material Accounting Policies

2.3.1 Foreign Currencies

Our consolidated financial statements are presented in Euros, which is also our functional currency. For each entity, the Group determines the functional currency, and items included in the consolidated financial statements of such entities are measured using that functional currency. We use the direct method of consolidation and, on disposal of a foreign operation, the gain or loss that is reclassified to the consolidated statements of profit or loss reflects the amount that arises from using this method.

Transactions and Balances

Transactions in foreign currencies are initially recorded by the Group's entities at their respective functional currency spot rates at the date the transaction first qualifies for recognition.

Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency spot rates of exchange at the reporting date.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions.

In determining the spot exchange rate to use on initial recognition of the related asset, expense or income (or part of it) on the derecognition of a non-monetary asset or non-monetary liability relating to advance consideration, the date of the transaction is the date on which the Group initially recognizes the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determines the transaction date for each payment or receipt of advance consideration.

Foreign Currency Translation

Foreign currency translation effects from the translation of operating activities include foreign exchange differences arising on operating items such as trade receivables and trade payables and are either shown as other operating income or expenses on a cumulative basis. Foreign currency translation effects presented within finance income and expenses include foreign exchange differences arising on financing items such as loans and borrowings as well as foreign exchange differences arising on cash and cash equivalents and are either shown as finance income or expenses on a cumulative basis.

Foreign Currency Translation on Consolidation

Upon consolidation, the assets and liabilities of foreign operations are translated into Euros at the rate of exchange prevailing at the reporting date and the transactions recorded in their consolidated statements of profit or loss are translated at exchange rates prevailing at the dates of the transactions.

The exchange differences arising on translation for consolidation are recognized in other comprehensive income. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is reclassified to profit or loss.

Any goodwill arising on the acquisition of a foreign operation and any fair value adjustments to the carrying amounts of assets and liabilities arising upon the acquisition are treated as assets and liabilities of the foreign operation and translated at the spot rate of exchange at the reporting date.

2.3.2 Current versus Non-Current Classifications

Assets and liabilities in the consolidated statements of financial position are presented based on current or non-current classification.

An asset is current when it is either: (i) expected to be realized or intended to be sold or consumed in the normal operating cycle, (ii) held primarily for the purpose of trading, (iii) expected to be realized within twelve months after the reporting period, or (iv) cash or cash equivalents, unless it is restricted from being exchanged or used to settle a liability for at least twelve months after the reporting period. All other assets are classified as non-current.

A liability is current when it is either: (i) expected to be settled in the normal operating cycle, (ii) held primarily for the purpose of trading, (iii) due to be settled within twelve months after the reporting period, or (iv) there is no unconditional right to defer the settlement of the liability for at least twelve months after the reporting period. The terms of the liability that could, at the option of the counterparty, result in its settlement by the issue of equity instruments do not affect its classification. The Group classifies all other liabilities as non-current.

Deferred tax assets and liabilities are classified as non-current assets and liabilities, respectively.

2.3.3 Revenue from Contracts with Customers

Revenue

Identification of the Contract

We generate revenues from collaboration and license agreements, which contain multiple elements, including licenses to use, research, develop, manufacture and commercialize candidates and products, research and development services as well as obligations to develop and manufacture preclinical and clinical material and products. We determined that those collaboration and license agreements qualify as contracts with customers. A contract is an agreement between two or more parties that establishes enforceable rights and obligations.

Identification of Performance Obligations

Our customer contracts often include bundles of licenses, goods and services. If the granting of a license is bundled together with delivering of goods and or the rendering of services, it is assessed whether these agreements are comprised of more than one performance obligation. A performance obligation is only accounted for as the grant of a license if the grant of a license is the sole or the predominant promise of the performance obligation.

Determining Transaction Prices

We apply judgment when determining the consideration that is expected to be received. If the consideration in an agreement includes a variable amount, we estimate the amount of consideration to which we will be entitled in exchange for transferring the goods to the customer. At contract inception, the variable consideration is estimated based on the most likely amount of consideration expected from the transaction and constrained until it is highly probable that a significant revenues reversal in the amount of cumulative revenues recognized will not occur when the associated uncertainty with respect to the variable consideration is subsequently resolved. The estimated revenues are updated at each reporting date to reflect the current facts and circumstances.

Allocation of Transaction Prices

If a contract with a customer contains more than one performance obligation, the transaction price is allocated to each performance obligation based on relative standalone selling prices. We have established the following hierarchy to determine the standalone selling prices.

- Where standalone selling prices for offered licenses, goods or services are observable and reasonably consistent across customers, our standalone selling price estimates are derived from our respective pricing history. However, due to the limited number of customers and the limited company history, this approach can rarely be used.
- Where sales prices for an offering are not directly observable or highly variable across customers, we follow a cost-plus-margin approach.
- For offerings that have highly variable pricing and lack substantial direct costs to estimate based on a cost-plus-margin approach, we allocate the transaction price by applying a residual approach.

Judgment is required when estimating standalone selling prices.

Recognition of Revenues

For each separate performance obligation, it is evaluated whether control is transferred either at a point in time or over time. For performance obligations that are satisfied over time, revenues are recognized based on a measure of progress, which depicts the performance in transferring control to the customer. Under the terms of our licensing arrangements, we provide the licensee with a research and development license, which represents a right to access our intellectual property as it exists throughout the license period (as our intellectual property is still subject to further research). Therefore, the promise to grant a license is accounted for as a performance obligation satisfied over time as our customers simultaneously receive and consume the benefits from our performance.

Revenues based on the collaboration partners' gross profit, which is shared under the respective collaboration agreements, are recognized based on the sales-based or usage-based royalty exemption; *i.e.*, when the underlying sales occur, which is when the performance obligation has been satisfied. As described further in Note 3, judgment is applied to certain aspects when accounting for the collaboration agreements.

Revenue arrangements that involve two or more partners who contribute to the provision of a specific good or service to a customer are assessed in terms of principal-agent considerations in order to determine the appropriate treatment for the transactions between us and the collaborator and the transactions between us and other third parties. The classification of transactions under such arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. Any consideration related to activities in which we are considered the principal, which includes being in control of the good or service before such good or service is transferred to the customer, is accounted for as gross revenues. Any consideration related to activities in which we are considered the agent is accounted for as net revenues.

Revenues from the sale of pharmaceutical and medical products (*e.g.*, COVID-19 vaccine sales and other sales of peptides and retroviral vectors for clinical supply) are recognized when we transfer control of the product to the customer. Control of the product normally transfers when the customer gains physical possession and we have not retained any significant risks of ownership or future obligations with respect to the product. In general, payments from customers are due within 30 days after invoice. However, with respect to our collaboration with Pfizer Inc., or Pfizer, there is a significant time lag between when revenues are recognized and the payments are received. The contractual settlement of the gross profit share has a temporal offset of more than one calendar quarter. As Pfizer's financial quarter for subsidiaries outside the United States differs from ours, it creates an additional time lag between the recognition of revenues and the payment receipt.

For certain contracts, the finished product may temporarily be stored at our location under a bill-and-hold arrangement. Revenues from bill-and-hold arrangements are recognized at the point in time when the customer obtains control of the product and all of the following criteria have been met: (i) the arrangement is substantive; (ii) the product is identified separately as belonging to the customer; (iii) the product is ready for physical transfer to the customer; and (iv) we do not have the ability to use the product or direct it to another customer. In determining when the customer obtains control of the product, we consider certain indicators, including whether title and significant risks and rewards of ownership have transferred to the customer and whether customer acceptance has been received.

Contract Balances

Contract Assets

A contract asset is the right to consideration in exchange for goods or services transferred to the customer. If we transfer goods or services to a customer before the customer pays the respective consideration or before payment is due, a contract asset is recognized for the earned consideration that is conditional.

Trade Receivables

A receivable represents our right to an amount of consideration that is unconditional *i.e.*, only the passage of time is required before payment of the consideration is due).

Contract Liabilities

A contract liability is the obligation to transfer goods or services to a customer for which we have received consideration (or an amount of consideration is due) from the customer. If a customer pays consideration before we transfer goods or services to the customer, a contract liability is recognized when the payment is made or when the payment is due

(whichever is earlier). Contract liabilities are recognized as revenue when we fulfill our performance obligations under the contract.

Refund Liabilities

A refund liability is a consideration which has been received but which will need to be refunded to the customer in the future as it represents an amount to which we are ultimately not entitled under the contract. A refund liability is measured at the amount of consideration received (or receivable) to which we do not expect to be entitled (*i.e.*, amounts not included in the transaction price). We update our estimates of refund liabilities (and the corresponding change in the transaction price) at the end of each reporting period.

2.3.4 Research and Development Expenses

Research and development costs are expensed in the period in which they are incurred. Regarding internal projects, we consider that regulatory approval and other uncertainties inherent in the development of new products preclude the capitalization of internal development expenses as an intangible asset until marketing approval from a regulatory authority is obtained. Payments made to third parties, such as contract research and development organizations as compensation for subcontracted research and development, that are deemed not to transfer intellectual property are expensed as internal research and development expenses in the period in which they are incurred. Such payments are only capitalized if they meet the criteria for recognition of an internally generated intangible asset, usually when marketing approval has been received from a regulatory authority. We have entered into agreements under which third parties grant licenses to us, which are known as in-license agreements. If in-licensing results in consideration for the acquisition of intellectual property that meets the definition of an identifiable asset, this is capitalized as an intangible asset unless the respective intellectual property is mainly used as part of our general ongoing research and development activities without any intent to market the respective product as such. If the transaction also includes research and development services to be provided by the licensor, the share of consideration attributable to these services is recognized in research and development expenses in line with the performance of the services. Sales-based milestone or royalty payments incurred under license agreements after the approval date of the respective pharmaceutical product are recognized as expenses in cost of sales as incurred.

Subsequent internal research and development costs in relation to intellectual property rights are expensed because the technical feasibility of the internal research and development activity can only be demonstrated by the receipt of marketing approval for a related product from a regulatory authority in a major market.

Prior to the second quarter of 2023, we had assessed that inventory produced prior to successful regulatory approval did not meet the criteria for capitalization as an asset, and accordingly expensed the costs of pre-launch inventory as research and development costs. Based on the experience of the past years and the developments since our COVID-19 vaccine was first authorized or approved for emergency or temporary use, our assessment regarding the potential to produce economic benefits changed. Beginning with the second quarter of 2023, pre-launch products from the *Comirnaty* product family with their potential for economic benefit fulfill the recognition criteria for an asset under the IFRS Conceptual Framework. At each reporting date, the respective inventory is measured at the lower of cost and net realizable value. However, because it is not probable until regulatory approval is obtained, we consider the net realizable value to be zero, as this is the probable amount expected to be realized from its sale until approval is obtained. The write-down is recognized in the statements of profit or loss as research and development expenses. If regulatory approval for a product candidate is obtained, the relevant write-down would be reversed to a maximum of the original cost. Subsequently, inventory is recognized as cost of sales. This reassessment has been treated as a change in estimate and the impacts on current period inventories, cost of sales and research and development expenses are described in Note 7.1.

2.3.5 Government Grants

Government grants and similar grants which are accounted for in accordance with IAS 20 are recognized where there is reasonable assurance that the grant will be received and all attached conditions will be complied with. When the grant relates to an expense item, it is recognized as other income on a systematic basis over the periods that the related costs for which the grant is intended to compensate are expensed. When the grant relates to an asset, it is recognized as deferred income within the consolidated statements of financial position. Other income is subsequently recognized in our consolidated statements of profit or loss over the useful life of the underlying asset subject to funding.

2.3.6 Taxes

Current Income Tax

Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted at the reporting date in the countries where the Group operates and generates taxable income.

In addition, current income taxes presented for the period include adjustments for uncertain tax payments or tax refunds for periods not yet finally assessed by tax authorities, excluding interest expenses and penalties on the underpayment of taxes. In the event that amounts included in the tax return are considered unlikely to be accepted by the tax authorities (uncertain tax positions), a provision for income taxes is recognized.

Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

Deferred Tax

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date.

Deferred tax liabilities are recognized for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; or
- in respect of taxable temporary differences associated with investments in subsidiaries, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognized for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, the carry forward of unused tax credits and unused tax losses can be utilized, except:

- when the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; or
- in respect of deductible temporary differences associated with investments in subsidiaries, deferred tax assets are recognized only to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilized.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year in which the asset is realized, or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Unrecognized deferred tax assets are re-assessed at each reporting date and are recognized to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Recognition of Taxes

Current and deferred tax items are recognized similarly to the underlying transaction either in profit or loss, other comprehensive income or directly in equity.

Current tax assets and current tax liabilities are offset if, and only if, we have a legally enforceable right to set off the recognized amounts and intend either to settle on a net basis, or to realize the asset and settle the liability simultaneously. Deferred tax assets and deferred tax liabilities are only offset when we have a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the

same taxation authority on either (i) the same taxable entity or (ii) different taxable entities, which intend either to settle current tax liabilities and assets on a net basis, or to realize the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

Sales Tax

Expenses and assets are recognized net of sales tax, except when the sales tax incurred on a purchase of assets or services is not recoverable from the taxation authority.

The net amount of sales tax recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the consolidated statements of financial position.

Future Tax Legislation

Based on the Organisation for Economic Co-operation and Development (OECD) Base Erosion and Profit Shifting (BEPS) project to tackle tax avoidance, the OECD/G20 Inclusive Framework (an association of about 140 countries) decided to introduce a global minimum taxation for large multinational groups (known as Pillar 2). The Global Anti-Base Erosion Rules are intended to ensure that large multinational groups pay a minimum level of tax on the income arising in each jurisdiction where they operate. In December 2021, the OECD published its Model Rules, which serve as a draft bill for implementation into national domestic law, followed by guidelines and commentaries published in March 2022. In December 2022, the EU adopted a corresponding directive (EU 2022/2523) that obliges EU member states to transpose the rules into national domestic law. If the effective tax rate in any jurisdiction is below the minimum rate (15%), the Group may be subject to the so-called top-up tax or a so-called qualified domestic minimum top-up tax.

Several jurisdictions in which the Group operates have transposed the OECD Model Rules into national domestic law and brought them into force. In addition, the Group is closely following the progress of the legislative process in each country in which the Group operates. As of the balance sheet date, the BEPS Pillar 2 regulations (MinBestRL UmsG) had already been transposed into German law (MinStG). The date of application of the law in Germany is for financial years beginning after December 30, 2023. Subsequently, as the OECD Model Rules have entered into force in Germany, the Group is obliged to file top-up tax information returns for all entities which are part of the Group, beginning in financial year 2024. The Group falls within the scope of these regulations. The Group carried out an analysis as of the reporting date to determine the fundamental impact and the jurisdictions in which the Group is exposed to possible effects in connection with a Pillar 2 top-up tax.

Based on this analysis, no countries were identified in which the Group would be materially affected by a Pillar 2 top-up tax. Consequently, the average effective Group tax rate would not have changed if the Pillar 2 legislation had already been in force on the balance sheet date. BioNTech applies the exception in IAS 12, according to which no deferred tax assets and liabilities in connection with the second income taxes of the second pillar of the OECD are recognized and no disclosures are made.

2.3.7 Business Combinations and Goodwill

Business combinations are accounted for using the acquisition method. The cost of an acquisition is measured as the aggregate of the consideration transferred, which is measured at acquisition date fair value, and the amount of any non-controlling interests in the acquiree.

Goodwill is initially measured at cost as the excess of the aggregate of the consideration transferred and the amount recognized for non-controlling interests and any previous interest held over the net identifiable assets acquired and liabilities assumed.

Costs related to executing business combinations are recognized when they are incurred and are classified as general and administrative expenses.

After initial recognition, goodwill is tested at least annually or when there is an indication for impairment. See Note 2.3.10 For the purpose of impairment testing, goodwill acquired in a business combination is, from the acquisition date, allocated to each of the cash-generating units that are expected to benefit from the combination, irrespective of whether other assets or liabilities of the acquiree are assigned to those units.

Where goodwill has been allocated to a cash-generating unit (CGU) and part of the operation within that unit is disposed of, the goodwill associated with the operation disposed of is included in the carrying amount of the operation when determining the gain or loss on disposal. Goodwill disposed of in these circumstances is measured based on the relative values of the operation disposed of and the portion of the cash-generating unit retained.

2.3.8 Intangible Assets

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is their fair value at the date of acquisition. Following initial recognition, intangible assets are carried at cost less any accumulated amortization and accumulated impairment losses.

The portion of the consideration in in-licensing agreements paid by us to acquire intellectual property is recognized as an intangible asset. If in-licensing includes research and development services, the share of consideration attributable to these services is deferred and recognized in research and development expenses according to the utilization thereof. Payments depending on the achievement of specific milestones as part of the purchase of intangible assets, except for intangible assets acquired in a business combination, are recognized as subsequent acquisition cost of the intangible asset and as a financial liability once the milestone is reached.

The useful lives of intangible assets are assessed as either finite or indefinite.

Intangible assets with finite lives are amortized generally on a straight-line basis over the useful life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization period and the amortization method for an intangible asset with a finite useful life are reviewed at the end of each reporting period at the least. The amortization expense on intangible assets with finite lives is recognized in the consolidated statements of profit or loss in the expense category that is consistent with the function of the intangible assets.

A summary of the useful lives applied to the Group's intangible assets is as follows:

Intangible assets	Useful life (years)
Intellectual property rights	8-20
Licenses	3-20
Software	3-8

Intangible assets with indefinite useful lives are tested for impairment at least annually, or when there is an indication for impairment, either individually or at the level of a cash-generating unit (see Note 2.3.10 for further details). In the case of intangible assets not yet available for use, the point in time from which a capitalized asset can be expected to generate economic benefit for the Group cannot be determined. Such assets are not amortized, and therefore classified as having an indefinite useful life. The intangible assets not yet available for use are tested for impairment annually, or when there is an indication for impairment on an individual basis. The assessment of indefinite life is reviewed annually to determine whether the indefinite life continues to be supportable. If not, the change in useful life from indefinite to finite is made on a prospective basis.

We have classified advanced payments on intangible assets as intangible assets that are not yet ready for use. Advanced payments on intangible assets are tested for impairment on an annual basis.

An intangible asset is derecognized upon disposal (*i.e.*, at the date the recipient obtains control) or when no future economic benefits are expected from its use or disposal. Any gain or loss arising upon derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the consolidated statements of profit or loss.

See Note 2.3.4 for further details in connection with our accounting of internally generated intangible assets.

2.3.9 Property, Plant and Equipment

Construction in progress is stated at cost. Property, plant and equipment are stated at cost, net of accumulated depreciation and accumulated impairment losses, if any. Such cost includes the cost of replacing part of the property, plant and equipment if the recognition criteria are met. All other repair and maintenance costs are expensed as incurred.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets, as follows:

Property, plant and equipment	Useful life (years)
Buildings	10-33
Equipment, tools and installations	7-18

Operating and business equipment has a useful life of 1-10 years and is reported under equipment, tools and installations due to immateriality.

An item of property, plant and equipment initially recognized is derecognized upon disposal (*i.e.*, at the date the recipient obtains control) or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the consolidated statements of profit or loss when the asset is derecognized.

The residual values, useful lives and methods of depreciation of property, plant and equipment are reviewed at each financial year-end and adjusted prospectively, if appropriate.

2.3.10 Impairment of Non-Financial Assets

At each reporting date, we assess whether there is an indication that a non-financial asset may be impaired. Goodwill is tested for impairment at least annually. Impairment is determined for goodwill by assessing the recoverable amount of each cash-generating unit (or group of CGUs) to which the goodwill relates. If any indication exists, or when annual impairment testing is performed, we estimate the asset's or CGU's recoverable amount. The recoverable amount is the higher of an asset's or CGU's fair value less costs of disposal and its value in use. The recoverable amount is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets. If the asset does not generate independent cash inflows, the impairment test is performed for the smallest group of assets that generate largely independent cash inflows from other assets (CGU). When the carrying amount of an asset or cash-generating unit exceeds its recoverable amount, the asset or the non-current assets of the CGU are considered impaired and written down to their recoverable amount.

Impairment losses are recognized in the consolidated statements of profit or loss in expense categories consistent with the function of the impaired asset.

Intangible assets with an indefinite useful life are tested for impairment annually at the CGU level, as appropriate, and when circumstances indicate that the carrying value may be impaired.

Intangible assets not yet available for use are not amortized, but rather tested for impairment when a triggering event arises or at least once a year. The identification of triggering events takes place on a quarterly or on an ad hoc basis with the involvement of the responsible departments, taking internal and external information sources into consideration. The impairment test is performed annually or if there are indications of impairment by determining the asset's value in use. In assessing value in use, the estimated discounted future cash flows are based on long-term forecast calculations reflecting the asset's estimated product life cycles. The assumptions are based on internal estimates along with external market studies. The result of the valuation depends to a large extent on the estimates by the management of the future cash flows of the assets and the discount rate applied, and is therefore subject to uncertainty.

2.3.11 Financial Instruments

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity.

i) Financial Assets

Initial Recognition and Measurement

Financial assets mainly include money market funds, bank deposits and reverse repos, security investments, trade receivables, cash at banks as well as equity investments. Financial assets are initially measured at fair value as of the trade date and – depending on their classification – subsequently measured at amortized cost, fair value through other comprehensive income (OCI) or fair value through profit or loss.

Subsequent Measurement

The measurement of financial assets depends on their classification, as described below.

Financial Assets Measured at Amortized Cost

Financial assets measured at amortized cost include trade receivables and other financial assets generally measured using the effective interest rate (EIR) method. With respect to trade receivables, we applied the practical expedient, which means that they are measured at the transaction price determined in accordance with IFRS 15. Refer to the accounting policies in Note 2.3.3. Other financial assets measured at amortized cost are held to collect contractual cash flows, which are solely payments of principal and interest. Gains and losses are recognized in our consolidated statements of profit or loss when the financial asset is derecognized, modified or impaired.

Financial Assets Designated at Fair Value through OCI (Equity Instruments)

Upon initial recognition, we can irrevocably elect to classify equity investments as equity instruments designated at fair value through OCI if they meet the definition of equity under IAS 32 and are not held for trading. The classification is determined on an instrument-by-instrument basis. Gains and losses on these financial assets are never recycled to profit or loss. Dividends are recognized as other income in the consolidated statements of profit or loss when the right of payment has been established. Equity instruments designated at fair value through OCI are not subject to impairment assessment. We elected to irrevocably classify our non-listed and listed equity investments under this category. They are recognized using trade date accounting.

Financial Assets at Fair Value through Profit or Loss

Derivatives not designated as hedging instruments are measured at fair value through profit or loss. A financial asset exists if the derivative has a positive fair value.

Derecognition

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognized (i.e., removed from the consolidated statements of financial position) when the rights to receive cash flows from the asset have expired or have been transferred in terms of fulfilling the derecognition criteria.

Impairment of Financial Assets

An allowance for expected credit losses (ECLs) is considered for all non-derivative financial debt investments, including cash, time deposits and debt securities of the Group. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all of the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

Since our financial debt investments are considered to be investments with low risk, the expected credit loss in the upcoming twelve months is used to determine the impairment loss. Wherever a considerable increase in the default risk is assumed, the lifetime expected credit loss of the financial asset is considered.

For trade receivables and contract assets, the Group applies a simplified approach in calculating ECLs. This means that the Group does not track changes in credit risk, but instead recognizes a loss allowance based on lifetime ECLs at each reporting date. We have established an ECL model that is based on the probability of default (PD), considers the respective country default probabilities and takes the maturities into account. In order to determine the PD of companies, we use the maturities of the trade receivables and the score of the companies.

If there is objective evidence that certain trade receivables or contract assets are fully or partially impaired, additional loss allowances are recognized to account for expected credit losses. A debtor's creditworthiness is assumed to be impaired if there are objective indications that the debtor is in financial difficulties, such as the disappearance of an active market for its products or impending insolvency.

ii) Financial Liabilities

Financial liabilities are generally measured at amortized cost using the effective interest rate (EIR) method. Derivatives with negative fair values not designated as hedging instruments and liabilities for contingent consideration in business combinations are measured at fair value.

All financial liabilities are recognized initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

Financial liabilities measured at amortized cost include loans and borrowings, trade payables and other financial liabilities. They are measured at amortized cost using the EIR method. Gains and losses are recognized in the consolidated statements of profit or loss when the liabilities are derecognized as well as through the EIR amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the EIR. The EIR amortization is included as finance costs in the consolidated statements of profit or loss.

Derecognition

A financial liability is derecognized when the obligation under the liability is discharged or cancelled or expires. When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as the derecognition of the original liability and the recognition of a new liability. The difference in the respective carrying amounts is recognized in the consolidated statements of profit or loss.

iii) Expenses and Income from Exchange Forward Contracts

Effects from foreign exchange forward contracts, which are measured at fair value through profit or loss, are shown as either other operating income or other operating expenses on a cumulative basis and might switch between those two items during the year-to-date reporting periods.

2.3.12 Fair Value Measurement

Fair value is a market-based measurement. For some assets and liabilities, observable market transactions or market information is available. For other assets and liabilities, observable market transactions or market information might not be available. When a price for an identical asset or liability is not observable, another valuation technique is used. To increase consistency and comparability in fair value measurements, there are three levels of the fair value hierarchy:

- Level 1 contains the use of quoted prices in active markets for identical assets or liabilities.
- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability either directly or indirectly.
- Level 3 inputs are unobservable.

Within this hierarchy, estimated values are made by management based on reasonable assumptions, including other fair value methods.

For assets and liabilities that are recognized in the financial statements at fair value on a recurring basis, we determine whether transfers have occurred between levels in the fair value hierarchy by re-assessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

For the purpose of fair value disclosures, classes of assets and liabilities have been determined on the basis of the nature, characteristics and risks of the asset or liability and the level of the fair value hierarchy, as explained above.

2.3.13 Inventories

Inventories are valued at the lower of cost and net realizable value.

Costs incurred in bringing each product to its present location and condition are accounted for as follows:

- raw materials and supplies: purchase cost on a first-in / first-out basis; or
- unfinished goods and finished goods: cost of direct materials and labor, including both internal manufacturing and third-party contract manufacturing organizations, or CMOs, and a proportion of manufacturing overheads based on the normal operating capacity, but excluding borrowing costs.

Net realizable value is the estimated selling price in the ordinary course of business less estimated costs of completion and the estimated costs necessary to make the sale. Write-offs are recorded if inventories are expected to be unsaleable, do not fulfill the specification defined by our quality standards or if their shelf-life has expired. For our inventories subject to the collaboration partners' gross profit share mechanism, we consider the contractual compensation payments in the estimate of the net realizable value.

Beginning with the second quarter of 2023, pre-launch products from the *Comirnaty* product family with their potential for economic benefit fulfill the recognition criteria for an asset under the IFRS Conceptual Framework. At each reporting date, the respective inventory is measured at the lower of cost and net realizable value. However, because it is not probable until regulatory approval is obtained, we consider the net realizable value to be zero, as this is the probable amount expected to be realized from its sale until approval is obtained (see also Note 2.3.4 for further information on our assessment regarding the potential of our pre-launch products to produce economic benefits).

2.3.14 Cash and Cash Equivalents

Cash and cash equivalents comprise cash at banks and on hand and short-term investments that we consider to be highly liquid (including deposits, money market funds and reverse repos) with an original maturity of three months or less that are readily convertible to a known amount of cash and subject to an insignificant risk of changes in value. Deposits with an original maturity of more than three months are recognized as other financial assets.

2.3.15 Treasury Shares

We apply the par value method to our repurchases of outstanding American Depositary Shares, or ADSs. Accordingly, the nominal value of acquired treasury shares is deducted from equity and shown in the separate item "Treasury shares". Any premium paid in excess of the nominal value of a repurchased ADS is deducted from the capital reserve. On the trade date, we recognize a liability, and on the settlement date, we settle in cash. We recognize the foreign exchange differences that may occur between the trade and settlement date as profit or loss.

2.3.16 Leases

At the inception of a contract, we assess whether the contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. To assess whether a contract conveys the right to control the use of an identified asset, we assess whether:

- the contract involves the use of an identified asset – this may be specified explicitly or implicitly and should be physically distinct or represent substantially all of the capacity of a physically distinct asset. If the supplier has a substantive substitution right, then the asset is not identified;
- we have the right to obtain substantially all of the economic benefits from the use of the asset throughout the period of use; and
- we have the right to direct the use of the asset. We possess this right when we hold the decision-making rights that are most relevant to changing how and for what purpose the asset is used. In rare cases where the decision about how and for what purpose the asset is used is predetermined, the Group has the right to direct the use of the asset if either:
 - we have the right to operate the asset; or
 - we designed the asset in a way that predetermines how and for what purpose it will be used.

At inception or on reassessment of a contract that contains a lease component, the consideration in the contract is allocated to each lease component on the basis of their relative standalone prices. However, for leases of land and buildings in which we are a lessee, we have elected not to separate non-lease components, and instead account for the lease and non-lease components as a single lease component.

We recognize a right-of-use asset and a lease liability at the lease commencement date.

The right-of-use asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred and an estimate of the costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located, less any lease incentives received by the Group.

The right-of-use asset is subsequently depreciated using the straight-line method from the commencement date to the earlier of the end of the useful life of the right-of-use asset and the end of the lease term. The estimated useful lives of right-of-use assets are determined on the same basis as those of property, plant and equipment. In addition, the right-of-use asset is periodically reduced by impairment losses, if any, and adjusted for certain remeasurements of the lease liability.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the incremental borrowing interest rate implicit in the lease or, if that rate cannot be readily determined, the Group's incremental borrowing rate. Generally, the incremental borrowing rate is used as the discount rate.

Lease payments included in the measurement of the lease liability comprise the following:

- fixed payments, including in-substance fixed payments;
- variable lease payments that depend on an index or a rate, initially measured using the index or rate as of the commencement date;
- amounts expected to be payable under a residual value guarantee; and
- the exercise price under a purchase option that is reasonably certain to be exercised, lease payments in an optional renewal period if it is reasonably certain that the extension option is exercised, and penalties for early termination of a lease unless it is reasonably certain that the contract will not be terminated early.

The lease liability is subsequently measured at amortized cost using the EIR method. It is remeasured when there is a change in future lease payments arising from a change in an index or rate, if there is a change in the estimate of the amount expected to be payable under a residual value guarantee, or if we change our assessment of whether we will exercise a purchase, extension or termination option. When the lease liability is remeasured, a corresponding adjustment is made to the carrying amount of the right-of-use asset or is recorded in the consolidated statements of profit or loss if the carrying amount of the right-of-use asset has been reduced to zero.

Right-of-use assets are presented separately and lease liabilities are presented under "Financial liabilities" in the consolidated statements of financial position.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets or shorter lease term, as follows:

Right-of-use assets	Useful life or shorter lease term (years)
Buildings	2-25
Equipment, tools and installations	2-5
Production facilities	2-3
Automobiles	3-4

Short-Term Leases and Leases of Low-Value Assets

We have elected not to recognize right-of-use assets and lease liabilities for short-term leases of machinery that have a lease term of 12 months or less or leases of low-value assets. We recognize the lease payments associated with these leases as an expense in the consolidated statements of profit or loss on a straight-line basis over the lease term.

2.3.17 Provisions

Provisions are recognized when there is a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. When we expect some or all of a provision to be reimbursed, for example, under an insurance contract, the reimbursement is recognized as a separate asset, but only when the reimbursement is virtually certain.

A provision is also recognized for certain contracts with suppliers for which the unavoidable costs of meeting the obligations exceed the economic benefits expected to be received. The economic benefits considered in the assessment comprise the future benefits we are directly entitled to under the contract as well as the anticipated future benefits that are the economic consequence of the contract if these benefits can be reliably determined.

The expense relating to a provision is presented in the consolidated statements of profit or loss net of any reimbursement.

2.3.18 Share-Based Payments

Employees (and others providing similar services) receive remuneration in the form of share-based payments, which are settled in equity instruments (equity-settled transactions) or in cash (cash-settled transactions).

In accordance with IFRS 2, share-based payments are generally divided into cash-settled and equity-settled. Both types of payment transactions are measured initially at their fair value as of the grant date. The fair value is determined using an appropriate valuation model, further details of which are given in Note 16. Rights granted under cash-settled transactions are remeasured at fair value at the end of each reporting period until the settlement date. The cost of share-based payment awards is recognized over the relevant service period, applying either the straight-line method or the graded vesting method, where applicable.

These costs are recognized in cost of sales, research and development expenses, sales and marketing expenses or general and administrative expenses, together with a corresponding increase in equity (other reserves) or other liabilities, over the period in which the service is provided (the vesting period). The cumulative expense recognized for cash- and equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired, and also reflects the best estimate of the number of equity instruments expected to ultimately vest.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of our best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

If we have a choice of settling either in cash or by providing equity instruments, the rights granted are accounted for as an equity-settled transaction, unless there is a present obligation to settle in cash.

If, due to local tax regulations, an amount is withheld for the employee's tax obligations and paid directly to the tax authorities in cash on the employee's behalf, the entire share-based payment program remains an equity-settled plan based on the IFRS 2 classification. Accordingly, the amount withheld for the employee's tax obligations expected to be paid directly to the tax authorities is reclassified from "Other reserves" to "Other non-financial liabilities".

2.3.19 Cash Dividend

We recognize a liability to pay a dividend when the distribution is authorized. As per the corporate laws of Germany, a distribution is authorized when it is approved by the general shareholder meeting. A corresponding amount is recognized directly in equity.

2.4 Standards Applied for the First Time

In 2023, the following potentially relevant new and amended standards and interpretations became effective, but did not have a material impact on our consolidated financial statements:

Standards / Interpretations	Date of application
IFRS 17 Insurance Contracts	January 1, 2023
Amendments to IFRS 17 Insurance contracts: Initial Application of IFRS 17 and IFRS 9 – Comparative Information	January 1, 2023
Amendments to IAS 1 and IFRS Practice Statement 2: Disclosure of Accounting Policies	January 1, 2023
Amendments to IAS 8 Accounting policies, Changes in Accounting Estimates and Errors: Definition of Accounting Estimates	January 1, 2023
Amendments to IAS 12 Income Taxes: Deferred Tax related to Assets and Liabilities arising from a Single Transaction	January 1, 2023
Amendments to IAS 12 Income taxes: International Tax Reform – Pillar Two Model Rules	January 1, 2023

2.5 Standards Issued but Not Yet Effective

The new and amended standards and interpretations that are issued but not yet effective by the date of issuance of the financial statements and that might have an impact on our financial statements are disclosed below. We have not adopted any standards early and intend to adopt these new and amended standards and interpretations, if applicable, when they become effective.

Standards / Interpretations	Date of application
Amendments to IFRS 16 Leases: Lease Liability in a Sale and Leaseback	January 1, 2024
Amendments to IAS 7 Statement of Cash Flows and IFRS 7 Financial Instruments: Disclosures: Supplier Finance Arrangements	January 1, 2024
Amendments to IAS 1 Presentation of Financial Statements: Classification of Liabilities as Current or Non-Current	January 1, 2024
Amendments to IAS 1 Presentation of Financial Statements: Non-current Liabilities with Covenants	January 1, 2024
Amendments to IAS 21 The Effects of Changes in Foreign Exchange Rates: Lack of Exchangeability	January 1, 2025

We do not expect a significant impact from the application of any of these standards and amendments.

3 Significant Accounting Judgements, Estimates and Assumptions

The preparation of the consolidated financial statements requires management to make judgments, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, the accompanying disclosures and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

Significant accounting judgments, as well as key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below. We based our assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond the control of the Group. Such changes are reflected in the assumptions when they occur.

Revenues from Contracts with Customers

We applied the following judgments, estimates and assumptions that significantly affect the determination of the amount and timing of revenues from contracts with customers:

Identification and Determination of Performance Obligations

We generate revenues from collaboration and license agreements, which contain multiple elements, including licenses to use, research, develop, manufacture and commercialize candidates and products, research and development services as well as obligations to develop and manufacture preclinical and clinical material and products. We determined that those collaboration and license agreements qualify as contracts with customers. A contract is an agreement between two or more parties that establishes enforceable rights and obligations. At inception of each agreement, we apply judgment when determining which promises represent distinct performance obligations. If promises are not distinct, they are combined until the bundle of promised goods and services is distinct. For some agreements, this results in accounting for goods and services promised in a collaboration and license agreement as a single performance obligation with a single measure of progress. For these combined performance obligations, we assess which of these promises is the predominant promise to determine the nature of the performance obligation. When licenses are granted, we determined that the grant of the license is the predominant promise within the combined performance obligations. In our view, we grant our customers a right to access or a right to use our intellectual property due to the collaboration and license agreements.

Measurement of the Transaction Price

Our collaboration and license agreements often include variable consideration, which is contingent on the occurrence or non-occurrence of a future event (i.e., reaching a certain milestone). When determining deferred revenues from a collaboration and license agreement, we need to estimate the amount of consideration to which we will be entitled in exchange for transferring the promised goods or services to our customers.

As there are usually only two possible outcomes (i.e., milestone is reached or not), we have assessed that the method of the most likely amount is the best method to predict the amount of consideration to which we will be entitled. At contract inception, the most likely amount for milestone payments is estimated to be zero. We have assessed that the likelihood of achieving the respective milestone decreases depending on how far the expected date of achieving the milestone lies in the future. At each reporting date, we use judgment to determine when to include variable consideration in the transaction price in such a way that it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with respect to the variable consideration is subsequently resolved. We have concluded that future milestone payments are fully constrained at the end of the current financial year.

Future milestone payments would become unconstrained upon the satisfaction of the milestone event, specifically a development event, regulatory approval or achievement of a sales milestone.

Allocation of the Transaction Price to Performance Obligations and Revenue Recognition as Performance Obligations are Satisfied

We allocate the transaction price to performance obligations based on their relative standalone selling prices, which are generally based on our best estimates and interpretations of facts and circumstances of each contractual agreement and may require significant judgment to determine appropriate allocation.

Upfront payments and reimbursement for expenses are initially deferred on our consolidated statements of financial position. We assessed that no significant financing component exists within our collaboration agreements since the overall business purpose of advanced payments is to support the payment structure rather than to provide a significant benefit of financing. For performance obligations in which the costs vary based on progress, an input-based measure that takes into account cost incurred is the most reliable indicator of the progress of the related research activities. In other cases, revenue recognition on a straight-line basis may be the most reliable indicator of our performance toward complete satisfaction. If the contractual activities progress, the achievement of development milestones will be used to measure the progress toward complete satisfaction. We evaluate the measure of progress in each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and net profit or loss in the period of adjustment.

Upon successfully commercializing a pharmaceutical product, the collaboration and license agreements also provide for additional profit-sharing or tiered royalties earned when customers recognize net sales of licensed products as well as sales milestone payments. Revenue is recognized based on the sales-based or usage-based royalty exemption; *i.e.*, when, or as, the underlying sales occur, which is when the performance obligation has been satisfied.

Principal-Agent Considerations

Collaboration agreements that involve two or more partners who contribute to the provision of a specific good or service to a customer are assessed in terms of principal-agent considerations. Under our current collaboration agreements, the allocation of marketing and distribution rights defines territories in which the collaboration partner acts as a principal in each case. We recognize revenue net based on the collaboration partners' gross profit in territories where the partner is responsible for supply, and on a gross basis when directly supplying our customers in our territories when control has been transferred. Amounts paid to collaboration partners for their share of our profits earned where we are the principal in the transaction are recorded as cost of sales.

Pfizer Agreement Characteristics

With respect to our collaboration with Pfizer, commercial revenues are recognized based on our collaboration partner's gross profit from COVID-19 vaccine sales, which is shared under the respective collaboration agreement. In determining commercial revenues pursuant to this collaboration agreement, we are reliant on our collaboration partner for details regarding its gross profit for the period at hand. Some of the information which our collaboration partner provides us with to identify the gross profit is, by necessity, preliminary and subject to change.

Pfizer's gross profit share is calculated based on sales and takes into account transfer prices. The latter include manufacturing and shipping costs, which represent standard prices and include mark-ups on manufacturing costs as specified by the terms of the agreement. Manufacturing and shipping cost variances were considered as far as those have been identified. Nevertheless, those input parameters may be adjusted once actual costs are determined. The sales as reported by Pfizer have been used to estimate license obligations in terms of royalties and sales milestones. Sales milestones and royalties are recognized as they are earned by the partners. Sales milestones are shared equally, while royalty payments are borne by the partners on the basis of revenues in the territories for which the partners are responsible and subsequently deducted as cost under the gross profit shared. The estimated royalty fees applied to net sales reflect the license obligations to the extent currently identified from third-party contractual arrangements. Changes in estimates are accounted for prospectively, when determined.

Manufacturing cost variances include expenses from unused contract manufacturing capacities and overstock inventories finally scrapped. As only materialized costs – which means manufacturing capacities finally lapsed or inventories finally scrapped – are shared with the partner in a cash-effective manner, the gross profit share impact is anticipated once assessed as being highly probable to occur. Therefore, information on Pfizer's write-downs of inventories is considered. Any changes to this assessment will be recognized prospectively.

Pfizer's determination of manufacturing and shipping costs also affects the transfer prices that have been charged to COVID-19 vaccine supplies that it manufactures and supplies to us and may be subject to adjustment whenever manufacturing and shipping cost variances are identified. Likewise, our own cost of sales and the respective gross profit share owed to our partner may be adjusted prospectively, when changes are determined.

For contract balances related to the Pfizer agreement, see Note 6. Judgment is required in determining whether a right to consideration is unconditional and thus qualifies as a receivable.

Provisions and Contingencies

We are currently confronted with a number of claims and legal proceedings. They include claims from third parties demanding indemnification for alleged infringement of a third-party patent or other intellectual proprietary rights, as well as product liability claims. In respect of these matters, we assess whether provisions must be recorded and whether contingencies must be reported.

Due to uncertainties relating to these matters, provisions and contingencies are based on the best information available.

Significant judgment is required in the determination of whether and when a provision is to be recorded and what the appropriate amount for such provision should be. Notably, judgment is required in the following areas:

- Determining whether an obligation exists
- Determining the probability of an outflow of economic benefits
- Determining whether the amount of an obligation is reliably estimable
- Estimating the amount of the expenditure required to settle the present obligation

At the end of each reporting period, we reassess the potential obligations related to our pending claims and litigation and adjust our respective provisions and contingencies to reflect the current best estimate. In addition, we monitor and evaluate new information that we receive after the end of the respective reporting period, but before the consolidated financial statements are authorized for issue, in order to determine whether this provides additional information regarding conditions that existed at the end of the reporting period. Changes to estimates, assumptions and outcomes compared to previous estimates and assumptions could require material adjustments to the carrying amounts of the respective provisions recorded and additional provisions.

The expected timing or amounts of any outflows of economic benefits resulting from these lawsuits and claims are uncertain and difficult to estimate or even not estimable, as they generally depend on the duration of the legal proceedings and settlement negotiations required to resolve the litigation and claims and the unpredictability of the outcomes of legal disputes in several jurisdictions.

Disclosures in respect of third-party claims and litigation for which no provisions have been recognized are made in the form of contingent liabilities, unless a potential outflow of resources is considered remote. It is not practicable to estimate the financial impact of contingent liabilities due to the uncertainties around lawsuits and claims as outlined above.

For further disclosures and carrying amounts relating to provisions as well as contingencies, see Note 17 and Note 18.

Research and Development Expenses

The nature of our business and primary focus of our activities, including development of our platforms and manufacturing technologies, generate a significant amount of research and development expenses. Research costs are expensed as incurred. Development expenditures on an individual project are recognized as an intangible asset if, and only if, the capitalization criteria are met. Based on our assessment, we have concluded that, due to the inherent risk of failure in pharmaceutical development and the uncertainty of approval, these criteria are usually not met before regulatory approval is achieved. The related expenditure is reflected in the consolidated statements of profit or loss in the period in which the expenditure is incurred. We have entered into agreements under which third parties grant licenses to us, which are known as in-license agreements. If in-licensing results in consideration for the acquisition of intellectual property that meets the definition of an identifiable asset, this is capitalized as an intangible asset. If the transaction also includes research and development services to be provided by the licensor, the share of consideration attributable to these services is recognized in research and development expenses in line with the performance of the services. The allocation of consideration attributable to the acquisition of intellectual property and consideration attributable to the research and development services provided by the licensor requires management to make judgements and assumptions. These judgements and assumptions can materially affect our research and development expenses.

Business Combinations

In our accounting for business combinations, judgment is required in determining whether an intangible asset is identifiable and whether it should be recorded separately from goodwill. Additionally, estimating the acquisition-date fair values in conjunction with purchase price allocation involves estimation uncertainty and discretionary decisions. The necessary measurements are based on information available on the acquisition date and on expectations and assumptions that have been deemed reasonable by management. These judgements, estimates and assumptions can materially affect our financial position and profit.

Intangible Assets

Significant assumptions and estimates are required to determine the appropriate amount of amortization of intangible assets. They relate in particular to the determination of the underlying useful life. The useful life of an intangible asset is

based on our estimates regarding the period over which the intangible asset is expected to generate economic benefits for us.

Significant assumptions and estimates are also required for the identification of a potential need to recognize an impairment loss. These estimates include management's assumptions regarding future cash flow projections and economic risks that require significant judgment and assumptions about future developments. They can be affected by a variety of factors, including, but not limited to, changes in business strategy, internal forecasts and the estimation of weighted average cost of capital.

Changes to the assumptions underlying our assessment of the impairment of goodwill and intangible assets could require material adjustments to the carrying amount of our recognized goodwill and intangible assets, as well as to the amounts of impairment charges recognized in profit or loss.

Share-Based Payments

Determining the fair value of share-based payment transactions requires the most appropriate valuation for the specific program, which depends on the underlying terms and conditions. We used valuation models such as a binomial or Monte Carlo simulation model for the measurement of the cash- and equity-settled transactions' fair value, taking into account certain assumptions relating to a number of factors, including the volatility of the stock price, the determination of an appropriate risk-free interest rate, expected dividends and the probability of reaching a minimum hurdle to exercise the relevant options. For awards which were granted prior to the initial public offering, at a time where no quoted market prices existed, the valuation model assumptions included the option's underlying share price. For awards which were granted after the initial public offering, the grant date's share prices on the Nasdaq Global Select Market were included in the valuation.

A fluctuation assumption is applied when estimating the number of equity instruments for which service conditions are expected to be satisfied and will be revised if material differences arise. Ultimately, a true-up to the number satisfied by the settlement date will be recorded.

For further disclosures relating to share-based payments, see Note 16.

Income Taxes

We are subject to income taxes in more than one tax jurisdiction. Due to the increasing complexity of tax laws and the corresponding uncertainty regarding the legal interpretation by the fiscal authorities, tax calculations are generally subject to an elevated amount of uncertainty. To the extent necessary, possible tax risks are taken into account in the form of provisions.

We do not recognize or we would impair deferred tax assets if it is unlikely that a corresponding amount of future taxable profit will be available against which the deductible temporary differences, tax loss carry forwards and tax credits can be utilized. The assessment whether a deferred tax asset can be recognized or is impaired requires significant judgment, as we need to estimate future taxable profits to determine whether the utilization of the deferred tax asset is probable. In evaluating our ability to utilize our deferred tax assets, we consider all available positive and negative evidence, including the level of historical taxable income and projections for future taxable income over the periods in which the deferred tax assets are recoverable. Based on the requirements in IAS 12, to not place reliance on future events that are uncertain as they for example cannot be controlled, managements assessment takes particular into account the fact that there is an inherent risk of failure in pharmaceutical development and an uncertainty of approval which is dependent on external regulatory agencies' opinions. This also includes management's assessment on the character and amounts of taxable future profits, the periods in which those profits are expected to occur, and the availability of tax planning opportunities.

Our management continued to take the view that deferred tax assets on tax losses carried forward that relate to subsidiaries which have a loss-making history cannot be recognized. This includes the assessment that those subsidiaries have neither any taxable temporary differences nor any tax planning opportunities available that could support the recognition of deferred tax assets.

For further disclosures relating to deferred taxes, see Note 8.

4 Group Information

Information about Subsidiaries

The consolidated financial statements include the following subsidiaries:

Name	Country of incorporation	Registered office	% equity interest	
			December 31, 2023	December 31, 2022
BioNTech BioNTainer Holding GmbH	Germany	Mainz	100 %	100 %
BioNTech Cell & Gene Therapies GmbH	Germany	Mainz	100 %	100 %
BioNTech Delivery Technologies GmbH	Germany	Halle	100 %	100 %
BioNTech Diagnostics GmbH	Germany	Mainz	100 %	100 %
BioNTech Europe GmbH	Germany	Mainz	100 %	100 %
BioNTech Idar-Oberstein Services GmbH	Germany	Idar-Oberstein	100 %	100 %
BioNTech Individualized mRNA Manufacturing GmbH	Germany	Mainz	100 %	100 %
BioNTech Innovation and Services Marburg GmbH	Germany	Marburg	100 %	100 %
BioNTech Innovation GmbH	Germany	Mainz	100 %	100 %
BioNTech Innovative Manufacturing Services GmbH	Germany	Idar-Oberstein	100 %	100 %
BioNTech Manufacturing GmbH	Germany	Mainz	100 %	100 %
BioNTech Manufacturing Marburg GmbH	Germany	Marburg	100 %	100 %
BioNTech Real Estate Holding GmbH	Germany	Holzkirchen	100 %	100 %
BioNTech Real Estate Verwaltungs GmbH	Germany	Holzkirchen	100 %	100 %
InstaDeep DE GmbH	Germany	Berlin	100 %	n/a ⁽²⁾
JPT Peptide Technologies GmbH	Germany	Berlin	100 %	100 %
NT Security and Services GmbH	Germany	Mainz	100 %	100 %
reSano GmbH	Germany	Mainz	100 %	100 %
BioNTech Australia Pty Ltd.	Australia	Melbourne	100 %	100 %
BioNTech R&D (Austria) GmbH	Austria	Vienna	100 %	100 %
BioNTech (Shanghai) Pharmaceuticals Co. Ltd.	China	Shanghai	100 %	100 %
InstaDeep France SAS	France	Paris	100 %	n/a ⁽²⁾
Biopharma BioNTech Israel Ltd.	Israel	Tel Aviv	100 %	n/a ⁽¹⁾
New Technologies Re	Luxembourg	Luxembourg	100 %	n/a ⁽¹⁾
InstaDeep Nigeria Limited	Nigeria	Lagos	100 %	n/a ⁽²⁾
BioNTech Rwanda Ltd.	Rwanda	Kigali	100 %	100 %
BioNTech Sénégal Suarl	Senegal	Dakar	100 %	n/a ⁽¹⁾
BioNTech Pharmaceuticals Asia Pacific Pte. Ltd.	Singapore	Singapore	100 %	100 %
BioNTech Pharmaceuticals Spain S.L	Spain	Barcelona	100 %	n/a ⁽¹⁾
BioNTech Switzerland GmbH	Switzerland	Basel	100 %	n/a ⁽¹⁾
BioNTech Taiwan Co. Ltd.	Taiwan	Taipei	100 %	n/a ⁽¹⁾
InstaDeep Tunisia SARL	Tunisia	Tunis	100 %	n/a ⁽²⁾
BioNTech Turkey Tıbbi Ürünler Ve Klinik Araştırma Ticaret Anonim Şirketi	Türkiye	Istanbul	100 %	100 %
BioNTech UK Ltd.	United Kingdom	London	100 %	100 %
InstaDeep Ltd.	United Kingdom	London	100 %	5.3% ⁽²⁾
BioNTech Research and Development, Inc.	United States	Cambridge	100 %	100 %
BioNTech USA Holding, LLC	United States	Cambridge	100 %	100 %
BioNTech US Inc.	United States	Cambridge	100 %	100 %
BioNTech Delivery Technologies (US), LLC	United States	Cambridge	100 %	n/a ⁽²⁾
InstaDeep LLC	United States	Dover	100 %	n/a ⁽²⁾
JPT Peptide Technologies Inc.	United States	Cambridge	100 %	100 %

⁽¹⁾ Included during the year ended December 31, 2023.

⁽²⁾ Fully acquired during the year ended December 31, 2023.

All entities listed above are included in our consolidated financial statements.

Parent Company

ATHOS KG, Holzkirchen, Germany, is the sole shareholder of AT Impf GmbH, Munich, Germany, and beneficial owner of the following percentage of ordinary shares in BioNTech at the dates as indicated. ATHOS KG via AT Impf GmbH has de facto control over BioNTech based on its substantial shareholding, which practically enables it to exercise the majority of voting rights to pass resolutions at our Annual General Meeting, or AGM.

Name	Country of incorporation	Registered office	Ownership of ordinary shares in BioNTech (in %)	
			December 31, 2023	December 31, 2022
AT Impf GmbH	Germany	Munich	43.77 %	43.42 %

Entity with Significant Influence over the Group

Medine GmbH, Mainz, Germany, owned the following percentage of ordinary shares in BioNTech at the following dates as indicated:

Name	Country of incorporation	Registered office	Ownership of ordinary shares in BioNTech (in %)	
			December 31, 2023	December 31, 2022
Medine GmbH	Germany	Mainz	17.01 %	17.38 %

5 Business Combinations

Acquisition of InstaDeep Ltd.

In July 2023, we acquired InstaDeep Ltd., London, United Kingdom (InstaDeep), a leading global technology company in the field of artificial intelligence (AI) and machine learning, by purchasing 100% of the remaining shares in InstaDeep not already owned by us. The acquisition is intended to create a fully integrated, enterprise-wide capability that leverages AI and machine learning technologies across our therapeutic platforms and operations. InstaDeep also continues to provide its services to clients around the world in diverse industries, including in the technology, transport and logistics, and industrial and financial services sectors.

The completion of the acquisition took place in July 2023. We performed an allocation of the total consideration and the underlying assets acquired (including certain identified intangible assets such as InstaDeep's DeepChain technology and customer relationships) and liabilities assumed based on their fair values using the information available as of the

acquisition date. The total consideration and the fair values in accordance with IFRS 3 of the identified net assets acquired of InstaDeep as of July 31, 2023, are as follows:

<i>(in millions €)</i>	Fair value recognized on acquisition InstaDeep Ltd.
Assets	
Intangible assets	187.6
Property, plant and equipment	2.1
Right-of-use assets	0.7
Trade receivables	2.4
Financial assets - current	52.5
Cash and cash equivalents	21.2
Other assets non-current and current	8.7
Total assets	275.0
Liabilities	
Deferred tax liabilities	45.8
Other liabilities long-term and short-term	18.2
Total liabilities	64.0
Total identifiable net assets at fair value	211.0
Goodwill from the acquisition	306.5
Total consideration	517.5
Consideration	
Cash paid	358.1
Cash to be paid in 2024	4.0
Designated FX hedge	(8.1)
Shares transferred (approx. 1.1 million shares)	103.7
Contingent consideration	31.8
Previously held non-listed equity investment (stake of 5.3%)	27.9
Total consideration	517.5

The intangible assets acquired comprise DeepChain technology and customer relationships. Their fair values were determined based on the multi-period excess earnings method (MEEM) and amount to €176.0 million and €7.8 million respectively.

The fair value of the shares transferred is determined based on the number of shares transferred and the closing price of the ADSs as of July 31, 2023.

The acquisition of InstaDeep is a step acquisition in accordance with IFRS 3.41-3.42A since we already held a 5.3% interest prior to the acquisition. In prior reporting periods, we recognized changes in the value of this equity interest in other comprehensive income. The amount of the remeasurement to fair value that was recognized in other comprehensive income is recognized on the same basis as would be required if we disposed directly of the previously held equity interest. Based on the total consideration for the acquired shares (94.7%), the value of the already held shares is €27.9 million, which results in a loss of €2.2 million shown in other comprehensive income in the year ended December 31, 2023.

At the acquisition date, the contingent consideration was recognized at its fair value of €31.8 million based on cash flow projections in connection with performance-based future milestone cash payments to eligible shareholders after a three-year earn-out period. The lower end of the bandwidth of possible outcomes of the contingent consideration is zero; the upper limit is €124.6 million. In addition, €12.5 million of potential earn-out payments are considered remuneration and will be recognized as personnel expense over a three-year period in which services are to be provided.

Transaction costs of €6.0 million were expensed and are included in general and administrative expenses.

The goodwill mainly comprises the value of expected synergies from including AI and machine learning technologies across our therapeutic platforms and operations and intangible assets that are not recognized separately, such as the acquired skilled workforce and its know-how. Therefore, the goodwill is allocated almost in full to the CGU immunotherapies and to a minor extent to a CGU comprising the external InstaDeep business. The goodwill is not tax deductible.

Deferred tax liabilities relating to temporary differences of the assets acquired in the business combination were recognized in an amount of €45.8 million. In line with the deferred tax liabilities assumed, deferred tax assets relating to temporary differences and tax loss carry forwards which existed as of the acquisition date were recognized. The deferred tax assets and liabilities were offset to the extent that the conditions for offsetting were fulfilled.

Since the acquisition, InstaDeep's impact on our revenue and profit for the period has been immaterial. Accordingly, hypothetical amounts for our revenue and profit for the financial year, which were calculated on the assumption that the acquisition had taken place at the beginning of the year, would not materially differ from the actual figures reported.

6 Revenues from Contracts with Customers

6.1 Disaggregated Revenue Information

Set out below is the disaggregation of the Group's revenues from contracts with customers:

<i>(in millions €)</i>	Years ended December 31,		
	2023	2022	2021
Commercial revenues	3,815.5	17,194.6	18,874.0
COVID-19 vaccine revenues	3,776.2	17,145.2	18,806.8
<i>Sales to collaboration partners</i>	275.3	1,224.3	970.9
<i>Direct product sales to customers</i>	473.6	3,184.7	3,007.2
<i>Share of collaboration partners' gross profit and sales milestones</i>	3,027.3	12,736.2	14,828.7
Other sales	39.3	49.4	67.2
Research & development revenues from collaborations	3.5	116.0	102.7
Total	3,819.0	17,310.6	18,976.7

During the year ended December 31, 2023, revenues recognized from Pfizer Inc., or Pfizer (€3,293.0 million) and the German Federal Ministry of Health (€473.6 million), each account for more than 10% of total revenues. During the year ended December 31, 2022, revenues recognized from Pfizer (€13,795.8 million) and the German Federal Ministry of Health (€3,020.5 million) represented more than 10% of total revenues. During the year ended December 31, 2021, revenues recognized from Pfizer (€15,500.0 million) and the German Federal Ministry of Health (€1,945.6 million), accounted for more than 10% of total revenues. During the year ended December 31, 2023, based on the geographic region in which our customers and collaboration partners are located, we mainly recognized revenues in the United States (€3,010.9 million) and Germany (€482.7 million). During the year ended December 31, 2022, the main geographic regions were United States (€12,709.7 million) and Germany (€3,031.0 million). During the year ended December 31, 2021, the main geographic regions were United States (€14,636.5 million), Germany (€2,241.9 million) and Belgium (€675.0 million).

Commercial Revenues

During the year ended December 31, 2023, commercial revenues were recognized from the supply and sales of our COVID-19 vaccine worldwide. During the year ended December 31, 2023, our commercial revenues decreased in line with a lower COVID-19 vaccine market demand. In addition, write-downs by our collaboration partner Pfizer Inc. (Pfizer), significantly reduced our gross profit share and hence negatively influenced our revenues for the year ended December 31, 2023. We are the marketing authorization holder in the United States, the European Union, the United Kingdom, Canada and other countries, and holder of emergency use authorizations or equivalents in the United States (jointly with Pfizer) and other countries. Pfizer has marketing and distribution rights worldwide with the exception of China, Germany and Türkiye. Shanghai Fosun Pharmaceutical (Group) Co., Ltd, or Fosun Pharma, has marketing and distribution rights in China, Hong Kong special administrative region, or SAR, Macau SAR and the region of Taiwan. The allocation of marketing and distribution rights defines territories in which the collaboration partners act as a principal.

Sales to Collaboration Partners

Sales to collaboration partners represent sales of products manufactured by us to collaboration partners. Whenever responsibilities in the manufacturing and supply process of the COVID-19 vaccine shift and the COVID-19 vaccine is transferred, the vaccine is sold from one partner to the other. Under the collaboration with Pfizer, from time to time, those sales are significantly influenced by amounts due to write-downs of inventories as well as costs related to production capacities derived from contracts with CMOs that became redundant. Those costs represent accrued manufacturing variances and are charged to our partner once finally materialized. These manufacturing variances are reflected as transfer price adjustments once identified. The regular reassessment of these manufacturing variances may result in adjustments to the respective prior-period revenues. Sales to collaboration partners during the years ended December 31, 2023, 2022 and 2021 of €74.5 million, €850.0 million and €31.0 million, respectively, related to the aforementioned manufacturing variances.

Direct Product Sales to Customers

Direct product sales are recognized from supplying COVID-19 vaccine in our territories Germany and Türkiye. During the years ended December 31, 2023, 2022 and 2021, we recognized €473.6 million, €3,184.7 million and €3,007.2 million of revenues, respectively. The share of gross profit that we owe our collaboration partner Pfizer based on our sales is recognized as cost of sales.

Share of Collaboration Partners' Gross Profit and Sales Milestones

Based on COVID-19 vaccine sales in the collaboration partners' territories, we are eligible to receive a share of their gross profit, which represents a seasonally affected net figure and is recognized as collaboration revenue during the commercial phase, together with sales milestones. Manufacturing cost variances either reflected as transfer price adjustments as described above or resulting from costs highly probable to be incurred by the partner, were taken into account when determining the gross profit. During the year ended December 31, 2021, those revenues included €476.6 million of sales milestones.

The revenues from contracts with customers disclosed above were recognized as follows:

<i>(in millions €)</i>	Years ended December 31,		
	2023	2022	2021
Timing of revenue recognition			
<i>Goods and services transferred at a point in time</i>	776.3	4,447.2	4,034.3
<i>Goods and services transferred over time</i>	15.4	127.2	113.7
<i>Revenue recognition applying the sales-based or usage-based royalty recognition constraint model⁽¹⁾</i>	3,027.3	12,736.2	14,828.7
Total	3,819.0	17,310.6	18,976.7

⁽¹⁾ Represents sales based on the share of the collaboration partners' gross profit and sales milestones.

6.2 Contract Balances

<i>(in millions €)</i>	December 31, 2023	December 31, 2022
Trade and other receivables	2,155.7	7,145.6
Contract liabilities	751.8	125.5
Refund liabilities	—	24.4

Trade and other receivables significantly decreased compared to the previous year and predominantly comprise trade receivables from our COVID-19 collaboration with Pfizer as well as our direct product sales to customers in our territory. The contractual settlement of the gross profit share has a temporal offset of more than one calendar quarter. As Pfizer's financial quarter for subsidiaries outside the United States differs from ours, it creates an additional time lag between the recognition of revenues and the payment receipt. Consequently, as of December 31, 2023, our trade receivables included, in addition to the profit share for the fourth quarter of 2023, trade receivables which related to the gross profit share for the third quarter of 2023.

Contract liabilities significantly increased compared to the previous year as advance payments in connection with the amendment of the COVID-19 vaccine purchase agreement with the European Commission, or EC, were received. As of December 31, 2023, the contract liabilities included €386.4 million of such payments under our collaboration with Pfizer (COVID-19 vaccine), €302.3 million from the German Federal Ministry of Health and €62.3 million of remaining upfront fees from our collaboration agreement with Pfizer (Zoster) (as of December 31, 2022: €65.7 million of remaining upfront fees from collaboration and commercial supply agreements and €56.3 million of advance payments for future COVID-19 vaccine sales).

The refund liabilities recognized as of December 31, 2022, represented consideration which was refunded to the collaboration partner during the year ended December 31, 2023.

Set out below is the amount of revenue recognized for the periods indicated:

<i>(in millions €)</i>	Years ended December 31,		
	2023	2022	2021
Amounts included in contract liabilities at the beginning of the year	3.5	63.1	73.7

6.3 Performance Obligations

The contract liabilities allocated to the remaining performance obligations from collaboration or commercial supply agreements (unsatisfied or partially unsatisfied) as of year-end are as follows:

<i>(in millions €)</i>	December 31, 2023	December 31, 2022
Within one year	353.3	77.1
More than one year	398.5	48.4
Total	751.8	125.5

7 Income and Expenses

7.1 General Expenses

Cost of Sales

From the year ended December 31, 2022 to the year ended December 31, 2023, cost of sales decreased by €2,395.2 million or 80% from €2,995.0 million to €599.8 million, mainly due to recognizing lower cost of sales from our decreased COVID-19 vaccine sales, which included the share of gross profit that we owe our collaboration partner Pfizer based on our sales. In addition, cost of sales was impacted by expenses arising from inventory write-offs and expenses for production capacities derived from contracts with CMOs that became redundant. The effects were driven by reducing production capacities as well as further fostering the global production network with our collaboration partners during the year ended December 31, 2023. Based on the regulatory approval obtained with respect to our Omicron XBB.1.5-adapted monovalent COVID-19 vaccine during the third quarter of 2023, we reversed the initial write-down of pre-launch inventory recorded in research and development expensed to a maximum of the original cost of €46.9 million. Thereof €27.3 million resulted in cost of sales during the year ended December 31, 2023 as the respective inventory has been either sold or written down. The remainder is presented in inventories as of December 31, 2023 and amounted to €19.6 million. With respect to the year ended December 31, 2022 the amount was nil.

Research and Development Expenses

From the year ended December 31, 2022 to the year ended December 31, 2023, our research and development expenses increased by €246.1 million or 16% from €1,537.0 million to €1,783.1 million, mainly influenced by progressing clinical studies for pipeline candidates as well as by our newly acquired product candidates and the development of variant adapted COVID-19 vaccines. The increase was further driven by an increase in wages, benefits and social security expenses resulting from a significant increase in headcount.

Sales and Marketing Expenses

From the year ended December 31, 2022 to the year ended December 31, 2023, our sales and marketing expenses increased by €3.2 million or 5% from €59.5 million to €62.7 million, mainly due to increased expenses for setup and enhancement of commercial IT platforms and an increase in wages, benefits and social security expenses resulting from an increase in headcount.

General and Administrative Expenses

From the year ended December 31, 2022 to the year ended December 31, 2023, our general and administrative expenses increased by €13.3 million or 3% from €481.7 million to €495.0 million, mainly influenced by increased expenses for IT services as well as by wages, benefits and social security expenses resulting from an increase in headcount.

7.2 Other Operating Expenses

<i>(in millions €)</i>	Years ended December 31,		
	2023	2022	2021
Foreign exchange differences, net	252.0	—	—
Loss on derivative instruments at fair value through profit or loss	—	385.5	86.3
Litigation costs ⁽¹⁾	29.4	3.0	9.0
Other	11.6	21.5	8.1
Total	293.0	410.0	103.4

⁽¹⁾ Adjustments to prior-year figures relate to costs for external legal advice in connection with certain legal litigations from general and administrative expenses to other operating expense to reflect changes in internal reporting also in the external reporting.

During the year ended December 31, 2023, the other expenses increased compared to the year ended December 31, 2022, which was mainly derived from recognizing foreign exchange differences arising on operating items. The foreign exchange differences included in operating expenses primarily arose from valuing our U.S. dollar-denominated trade receivables which were mainly incurred under our COVID-19 collaboration with Pfizer, U.S. dollar-denominated trade

payables as well as U.S. dollar-denominated other financial liabilities which mainly relate to obligations incurred from our license agreements.

During the year ended December 31, 2022, the other operating expenses increased compared to the year ended December 31, 2021, mainly from recording the change in fair value of foreign exchange forward contracts that were entered into during the year ended December 31, 2022, to manage some of our transaction exposures but were not designated as hedging instruments under IFRS.

7.3 Other Operating Income

<i>(in millions €)</i>	Years ended December 31,		
	2023	2022	2021
Gain on derivative instruments at fair value through profit or loss	67.6	—	5.7
Government grants	2.2	1.4	137.2
Foreign exchange differences, net	—	727.4	446.3
Other	35.2	86.5	9.2
Total	105.0	815.3	598.4

During the year ended December 31, 2023, the other income decreased compared to the year ended December 31, 2022, as foreign exchange differences arising on operating items changed from a positive effect to a negative effect, which is recorded in other operating expenses (see Note 7.2).

During the year ended December 31, 2022, the other income increased compared to the year ended December 31, 2021, which was mainly due to recognizing foreign exchange differences arising on operating items. The foreign exchange differences included in operating income primarily arose from valuing our U.S. dollar-denominated trade receivables which were mainly incurred under our COVID-19 collaboration with Pfizer, U.S. dollar-denominated trade payables as well as U.S. dollar-denominated other financial liabilities which mainly relate to obligations incurred from our license agreements.

7.4 Finance Income

<i>(in millions €)</i>	Years ended December 31,		
	2023	2022	2021
Interest income	357.6	48.5	1.5
Fair value adjustments of financial instruments measured at fair value	162.0	216.8	—
Foreign exchange differences, net	—	65.0	66.2
Total	519.6	330.3	67.7

During the year ended December 31, 2023, the finance income increased compared to the year ended December 31, 2022, mainly due to interest income earned on bank deposits and financial securities as well as fair value adjustments in relation to our money market funds.

During the year ended December 31, 2022, the finance income included the final fair value measurement adjustments of the derivative embedded within the convertible note upon the early redemption of the convertible note as of March 1, 2022, the redemption date, as well as interest income from our bank deposits and increased compared to the year ended December 31, 2021.

7.5 Finance Expenses

<i>(in millions €)</i>	Years ended December 31,		
	2023	2022	2021
Foreign exchange differences, net	16.0	—	—
Fair value adjustments of financial instruments measured at fair value	—	—	277.8
Other	7.9	18.9	27.3
Total	23.9	18.9	305.1

During the year ended December 31, 2023, the finance expenses increased compared to the year ended December 31, 2022, mainly due to exchange differences derived from our foreign exchange bank deposits and cash accounts.

During the year ended December 31, 2022, the finance expenses decreased compared to the year ended December 31, 2021, mainly due to final settlement of the derivative embedded within the convertible note which led to financial income whereas during the year ended December 31, 2021, expenses in the amount of €277.8 million were derived from the respective fair value measurement adjustment.

7.6 Employee Benefits Expense

<i>(in millions €)</i>	Years ended December 31,		
	2023	2022	2021
Wages and salaries	617.8	544.8	345.9
Social security costs	76.7	58.6	31.7
Pension costs	4.1	2.1	1.2
Total	698.6	605.5	378.8

Wages and salaries include, among other things, expenses for share-based payments.

8 Income Tax

Income tax for the years ended December 31, 2023, December 31, 2022, and December 31, 2021, comprised current income taxes, other taxes and deferred taxes. We are subject to corporate taxes, the solidarity surcharge and trade taxes. Our corporate tax rate in the reporting year remained unchanged (15.0%) as did the solidarity surcharge (5.5%) whereas the average trade tax rate changed resulting in a combined income tax rate of 27.1% in the year ended December 31, 2023 (during the years ended December 31, 2022 and 2021: 27.2% and 30.7%, respectively). Deferred taxes are calculated at a rate of 27.1%. Current taxes for Austria are calculated at a corporate tax rate of 24.0%. Austria's decrease of its corporate tax rate down to 23.0% in 2024 is recognized from 2023 onwards for deferred taxes. BioNTech USA Holding, LLC is subject to Federal Corporate Income Tax (21.0%) as well as State Income Tax in various state jurisdictions (effective rate of 4.5%). The deferred tax rates calculations basis remained unchanged compared to the previous period.

The following table illustrates the current and deferred taxes for the periods indicated:

<i>(in millions €)</i>	Years ended December 31,		
	2023	2022	2021
Current income taxes	243.1	3,629.6	4,535.0
Deferred taxes	12.7	(109.9)	218.9
Income taxes	255.8	3,519.7	4,753.9

The following table reconciles the expected income taxes to the income tax expenses. The expected income taxes were calculated using the combined income tax rate of BioNTech SE applicable to the Group and mentioned above which was applied to profit before taxes to calculate the expected income taxes.

<i>(in millions €)</i>	Years ended December 31,		
	2023	2022	2021
Profit before tax	1,186.1	12,954.1	15,046.4
Expected tax credit	321.8	3,529.7	4,622.5
<i>Effects</i>			
Deviation due to local tax basis	6.6	8.9	9.1
Deviation due to deviating income tax rate (Germany and foreign countries)	(0.1)	7.3	9.4
Change in valuation allowance	(14.3)	30.6	3.0
Effects from tax losses and tax credits	(66.5)	23.2	19.5
Change in deferred taxes due to tax rate change	(2.4)	(2.3)	(7.5)
Non-deductible expenses	3.1	2.5	90.5
Non tax-effective income	(0.6)	(87.9)	(0.3)
Non tax-effective share-based payment expenses	7.7	8.7	15.5
Tax-effective equity transaction costs	—	—	(1.2)
Adjustment prior year taxes	5.5	(31.5)	(2.9)
Non-tax effective bargain purchase	—	—	(0.7)
Other effects	(5.0)	30.5	(3.0)
Income taxes	255.8	3,519.7	4,753.9
Effective tax rate	21.6 %	27.2%	31.6%

On November 15, 2018, we established a share option program pursuant to which we were permitted to grant selected employees and our Management Board options to receive shares in the Company. The program is designed as an Employee Stock Ownership Plan, or ESOP. We offered the participants a certain number of rights, or option rights, subject to their explicit acceptance. Grants under the ESOP took place from November 2018 until December 2019. An exercise of option rights in accordance with the terms of the ESOP gives a participant the right to obtain shares against payment of the exercise price. By way of an updated decision of the Supervisory Board at the end of September 2022 compared to the initial settlement mechanism, an ESOP settlement may be made by delivery to the participant of such number of ADSs equal to the net value of the exercised option rights after deduction of (i) the exercise price and (ii) the applicable wage taxes (including solidarity surcharge thereon and church tax, if applicable) and social security contributions resulting from such exercise. The respective number of ADS shall be settled with ADS acquired in the course of the share repurchase program. The applicable wage taxes (including solidarity surcharge thereon and church tax, if applicable) and social security contributions resulting from such exercise are paid in cash directly to the respective authorities. Expenses for taxation purposes resulting from the settlement are only recognized once the option rights have been exercised. After considering the settlements in the twelve months ended December 31, 2023 and taking into account the recognition criteria of IAS 12, a deferred tax is not recognized in our consolidated statement of financial position of €17.8 million which relates to future settlements.

The current tax savings associated with the excess were directly recognized in equity in a total amount of €19.8 million. Considering these tax amounts directly recognized in equity when calculating an effective tax rate, the tax rate would be decreased by about 1.6 percentage points.

The intended settlement mechanism of Option Rights of the Chief Executive Officer Grant (see Note 16.4 for plan details) led to a deferred tax asset in the total amount of €108.8 million as of December 31, 2023. Taking into account the

recognition criteria of IAS 12 this deferred tax asset is not recognized in our consolidated statements of profit or loss neither recognized directly in equity as other reserves in our consolidated statements of changes in stockholders' equity.

Taxes

Deferred taxes for the periods indicated relate to the following:

Year ended December 31, 2023

<i>(in millions €)</i>	January 1, 2023	Recognized in P&L	Recognized in OCI	Recognized directly in equity	December 31, 2023
Fixed assets	15.8	20.2	—	(44.4)	(8.4)
Right-of-use assets	(55.8)	(0.8)	—	—	(56.6)
Inventories	148.9	(35.3)	—	—	113.6
Trade and other receivables	(162.7)	72.7	—	—	(90.0)
Lease liabilities	55.2	2.0	—	—	57.2
Contract liabilities	(10.0)	(33.0)	—	—	(43.0)
Loans and borrowings	7.6	(2.8)	—	—	4.8
Net employee defined benefit liabilities	0.7	(0.1)	—	—	0.6
Share-based payments	188.4	12.0	—	(58.3)	142.1
Other provisions	11.0	(1.2)	—	—	9.8
Other (incl. deferred expenses)	61.5	(106.4)	—	—	(44.9)
Tax losses / tax credits	99.5	(5.1)	—	—	94.4
Deferred tax assets net (before valuation adjustment)	360.1	(77.8)	—	(102.7)	179.6
Valuation adjustment	(136.7)	65.1	—	(66.4)	(138.0)
Deferred tax assets / (liabilities), net (after valuation adjustment)	223.4	(12.7)	—	(169.1)	41.6
Thereof deferred tax assets	229.6	20.8	—	(169.1)	81.3
Thereof deferred tax liability	(6.2)	(33.5)	—	—	(39.7)

Year ended December 31, 2022

<i>(in millions €)</i>	January 1, 2022	Recognized in P&L	Recognized in OCI	Recognized directly in equity	December 31, 2022
Fixed assets	(6.5)	22.3	—	—	15.8
Right-of-use assets	(47.5)	(8.3)	—	—	(55.8)
Inventories	1.8	147.1	—	—	148.9
Trade and other receivables	(95.6)	(67.1)	—	—	(162.7)
Lease liabilities	48.7	6.5	—	—	55.2
Loans and borrowings	23.1	(15.5)	—	—	7.6
Contract liabilities	10.6	(20.6)	—	—	(10.0)
Net employee defined benefit liabilities	0.9	(0.5)	0.3	—	0.7
Other provisions	6.3	4.7	—	—	11.0
Share-based payments	—	8.5	—	179.9	188.4
Other (incl. deferred expenses)	1.6	59.9	—	—	61.5
Tax losses / tax credits	70.9	28.6	—	—	99.5
Deferred tax assets net (before valuation adjustment)	14.3	165.6	0.3	179.9	360.1
Valuation adjustment	(81.0)	(55.7)	—	—	(136.7)
Deferred tax assets / (liabilities), net (after valuation adjustment)	(66.7)	109.9	0.3	179.9	223.4

As of December 31, 2023, our accumulated tax losses comprised tax losses of German entities that were incurred prior to the establishment of a tax group with BioNTech SE or by entities that are not within the tax group (as of December 31, 2023: BioNTech Real Estate Verwaltungs GmbH; as of December 31, 2022: BioNTech BioNTainer Holding GmbH, BioNTech Idar-Oberstein Services GmbH, NT Security and Services GmbH, BioNTech Real Estate Verwaltungs GmbH and the Real Estate partnerships) or U.S. tax group. Up until the year ended December 31, 2022, our accumulated tax losses also comprised those of the German tax group. Our accumulated tax losses for the periods indicated amounted to the following:

<i>(in millions €)</i>	Years ended December 31,		
	2023	2022	2021
Corporate tax	260.7	352.3	272.0
Trade tax	140.1	204.1	170.6

<i>(in millions €)</i>	Years ended December 31,		
	2023	2022	2021
Federal tax credits	21.3	4.0	0.8
State tax credits	8.7	1.6	0.3

Up until the year ended December 31, 2023, deferred tax assets on tax losses were only partially recognized, as there was not sufficient probability in terms of IAS 12 that future taxable profits would have been available against which all the unused tax losses could have been utilized.

The amount of deductible temporary differences, unused tax losses, and unused tax credits for which no deferred tax asset is recognized in the statement of financial position as of December 31, 2023 is €531.5 million. Thus as of December 31, 2023, we have not recognized deferred tax assets for unused tax losses and temporary differences in an amount of €138.0 million (December 31, 2022: €136.7 million 31 December 2021 €81.0 million).

A reorganization of the intellectual property rights within the group became effective as of June 30, 2023 and July 1, 2023 which led to deferred tax effects in Germany, the U.S. and Austria. As a result, BioNTech SE recognized deferred tax assets and deferred tax income at the time of the transaction. In addition, this transaction led to a revaluation of previously unrecognized U.S. federal and state deferred tax assets, including unused tax losses and unused tax credits. As of December 31, 2022, there were unrecognized U.S. federal and state deferred tax assets of €128.9 million. As of December 31, 2023, it is considered highly probable that taxable profits for the U.S. tax group will be available against which the deferred tax assets can be utilized in the near future, fulfilling the requirements set out by IAS 12. Therefore we no longer continue to maintain the full non-recognition of deferred tax assets of our U.S. tax group as there will be future taxable profits available against which the unused tax losses and temporary differences can be utilized. As of December 31, 2023, we maintain the non-recognition of deferred tax assets for unused U.S. federal and state tax losses and tax credits at an amount of €31.9 million and €2.8 million, respectively, as there is not sufficient probability in terms of IAS 12 that future taxable income will be available against which these unused tax losses can be utilized. The material unrecognized U.S. federal and state tax losses and tax credits will begin to expire in 2036.

The Group does not recognize deferred tax liabilities for taxable temporary differences associated with investments in subsidiaries, in cases where the Group is able to control the timing of the reversal of the temporary difference and it is probable that the temporary differences will not reverse in the foreseeable future. The aggregate amount of temporary differences associated with investments in subsidiaries, for which deferred tax liabilities have not been recognized, is €2.8 million.

9 Earnings per Share

Basic earnings per share (EPS) is calculated by dividing the profit for the year attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year.

Diluted EPS is calculated by dividing the profit attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year, plus the weighted average number of ordinary shares that would be issued on conversion of all the dilutive potential ordinary shares into ordinary shares.

The following table reflects the income and share data used in the basic and diluted EPS calculations:

<i>(in millions €, except per share data)</i>	Years ended December 31,		
	2023	2022	2021
Profit attributable to ordinary equity holders of the parent for basic earnings	930.3	9,434.4	10,292.5
Weighted average number of ordinary shares outstanding for basic EPS	240.6	243.3	244.0
Effects of dilution from share options	2.1	6.5	15.7
Weighted average number of ordinary shares outstanding adjusted for the effect of dilution	242.7	249.8	259.7
Earnings per share			
Basic earnings for the period per share	3.87	38.78	42.18
Diluted earnings for the period per share	3.83	37.77	39.63

10 Other Intangible Assets and Goodwill

Goodwill

(in millions €)

	Goodwill
Acquisition costs	
As of January 1, 2022	57.8
Currency differences	3.4
As of December 31, 2022	61.2
As of January 1, 2023	61.2
Acquisition of subsidiaries and businesses	306.9
Currency differences	(5.6)
As of December 31, 2023	362.5

Intangible Assets with Indefinite Useful Lives

(in millions €)	CGU Immunotherapies		External Product Sales of JPT		External Business of InstaDeep		Total	
	As of December 31, 2023	As of December 31, 2022	As of December 31, 2023	As of December 31, 2022	As of December 31, 2023	As of December 31, 2022	As of December 31, 2023	As of December 31, 2022
Goodwill	352.2	60.7	0.5	0.5	9.8	—	362.5	61.2
Intangible assets with indefinite useful life	444.5	—	—	—	—	—	444.5	—
Total	796.7	60.7	0.5	0.5	9.8	—	807.0	61.2

For the year ended December 31, 2023, we have total goodwill of €362.5 million, which relates almost completely to the CGU immunotherapies. The CGU immunotherapies focuses on the development of therapies to address a range of rare and infectious diseases and comprises our broad pipeline that includes mRNA-based immune activators, antigen-targeting T cells and antibodies and defined immunomodulators of various immune cell mechanisms.

We performed our annual impairment test in October 2023.

The recoverable amount of the CGU immunotherapies has been determined based on a fair value less cost of disposal (FVLCD), which we derived based on our market capitalization as an observable input parameter.

The recoverable amount of the CGU JPT and the CGU external business of InstaDeep has been determined based on the value in use. In assessing value in use, the estimated future cash flows, which are derived based on the strategic business plan approved by the management, are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the assets. A long-term growth rate of 1.0% is applied to project future cash flows after the last year of the detailed planning period.

As a result of the analysis in October 2023, we did not identify an impairment for these CGUs.

Intangible assets with indefinite useful lives mainly comprised intangible assets not yet available for use of €443.5 million. Such assets are not amortized and therefore reviewed for impairment annually. An impairment test was performed on an individual basis of the assets in the fourth quarter of 2023. The recoverable amounts were determined based on value in use. The results did not give rise to any impairment losses.

Considering updated financial information regarding our COVID 19 vaccine business an additional impairment test for our CGU immunotherapies was performed as of December 31, 2023. The recoverable amount of the CGU immunotherapies was once again determined based on a fair value less cost of disposal (FVLCD), which we derived based on our market capitalization as of December 31, 2023.

As a result of the additional analysis for the CGU immunotherapies, we did not identify an impairment for the CGU immunotherapies. Even if our market capitalization had been approximately 10% lower, FVLCD would have still been above the respective carrying amount of the CGU.

The intangible assets resulting from licensing and collaboration agreements are combined into one class of assets due to their similar nature and use in our operations and are attributed to the CGU immunotherapies.

A sensitivity analysis of the key assumptions, future cash flows and weighted average cost of capital, was performed as part of the scheduled impairment testing of the intangible assets not yet available for use. The sensitivity analysis did not give rise to any impairment loss, either for a reduction of 10% in future cash flows or for a 10% increase in the weighted average cost of capital.

Other Intangible Assets

<i>(in millions €)</i>	Concessions, licenses, in-process R&D and similar rights	Advance payments	Total
Acquisition costs			
As of January 1, 2022	191.6	7.8	199.4
Additions	22.8	11.4	34.2
Disposals	(0.1)	—	(0.1)
Reclassifications	6.1	(6.1)	—
Currency differences	1.9	—	1.9
As of December 31, 2022	222.3	13.1	235.4
As of January 1, 2023	222.3	13.1	235.4
Additions	489.2	15.8	505.0
Acquisition of subsidiaries and businesses	187.4	—	187.4
Disposals	(1.6)	(1.6)	(3.2)
Reclassifications	4.9	(4.9)	—
Currency differences	(3.6)	—	(3.6)
As of December 31, 2023	898.6	22.4	921.0

<i>(in millions €)</i>	Concessions, licenses, in-process R&D and similar rights	Advance payments	Total
Cumulative amortization and impairment charges			
As of January 1, 2022	54.8	—	54.8
Amortization	22.0	—	22.0
Disposals	(0.1)	—	(0.1)
Currency differences	0.2	—	0.2
As of December 31, 2022	76.9	—	76.9
As of January 1, 2023	76.9	—	76.9
Amortization	40.5	—	40.5
Disposals	(0.3)	—	(0.3)
Currency differences	(0.2)	—	(0.2)
As of December 31, 2023	116.9	—	116.9

<i>(in millions €)</i>	Concessions, licenses, in-process R&D and similar rights	Advance payments	Total
Carrying amount			
As of December 31, 2022	145.4	13.1	158.5
As of December 31, 2023	781.7	22.4	804.1

The increase in other intangible assets by €645.6 million from December 31, 2022 to December 31, 2023 was mainly related to the acquisition of InstaDeep (see Note 5) and licenses fulfilling the definition of identifiable assets acquired. We entered into license and collaboration agreements in which we work together with partners to develop pharmaceutical products and, provided regulatory approval is granted, commercialize them. The upfront payments in connection with the license and collaboration agreements described below resulted in the recognition of intangible assets not yet available for use in the amount of €443.5 million and a prepayment for future development activities recognized in the other non-financial assets (€22.5 million as at December 31, 2023, see also Note 14).

In March 2023, we entered into license and collaboration agreements with Duality Biologics (Suzhou) Co. Ltd., Shanghai, China, or Duality, for exclusive licenses to two investigational ADC assets (BNT323/DB-1303 and BNT324/DB-1311) directed against targets expressed in a broad range of human cancers. In August 2023, we signed another exclusive agreement with Duality to develop, manufacture and commercialize an additional ADC, BNT325/DB-1305. Duality received upfront payments totaling \$220.0 million (€203.7 million) and is eligible to receive future milestone payments as well as tiered royalties.

In April 2023, we entered into a licensing and collaboration agreement with OncoC4 Inc., Rockville (Maryland), United States, or OncoC4, which includes joint development of BNT316/ONC-392 in a range of solid tumor indications, with the parties equally sharing development costs for such joint development studies. BioNTech holds the exclusive worldwide commercialization rights for this product candidate. OncoC4 received an upfront payment of \$200.0 million (€181.5 million, thereof €125.2 million paid for the acquisition of an intangible asset) and is eligible to receive future milestone payments as well as tiered royalties.

In November 2023, we entered into a strategic research collaboration and worldwide license agreement with MediLink Therapeutics (Suzhou) Co., Ltd., or MediLink Therapeutics, for the development of a next-generation ADC, BNT326/YL202, against Human Epidermal Growth Factor Receptor 3 (HER3). MediLink Therapeutics received an upfront payment of \$70.0 million (€64.1 million) and is eligible to receive future milestone payments as well as tiered royalties.

In December 2023, we entered into an exclusive global license and collaboration with Biotheus Inc., or Biotheus, under which we will be developing, manufacturing and commercializing Biotheus' bispecific antibody candidate BNT327/PM8002 globally ex-Greater China. We agreed to an upfront payment of \$55.0 million (€50.6 million) plus future milestone and royalty payments.

In July 2023, in connection with the acquisition of InstaDeep we acquired DeepChain technology. As of December 31, 2023 the book value of DeepChain technology amounted to €163.3 million with a remaining useful life of 6.6 years.

11 Property, Plant and Equipment

<i>(in millions €)</i>	Land and buildings	Equipment, tools and installations	Construction in progress and advance payments	Total
Acquisition and production costs				
As of January 1, 2022	104.1	198.3	94.3	396.7
Additions	100.2	46.7	182.3	329.2
Disposals	—	(1.1)	(0.5)	(1.6)
Reclassifications	12.0	28.2	(40.2)	—
Currency differences	0.7	0.9	(0.4)	1.2
As of December 31, 2022	217.0	273.0	235.5	725.5
As of January 1, 2023	217.0	273.0	235.5	725.5
Additions	9.7	50.3	189.4	249.4
Acquisition of subsidiaries and businesses	—	2.1	—	2.1
Disposals	—	(2.4)	(0.2)	(2.6)
Reclassifications	9.3	22.3	(31.6)	—
Currency differences	(0.6)	(1.2)	(3.6)	(5.4)
As of December 31, 2023	235.4	344.1	389.5	969.0

<i>(in millions €)</i>	Land and buildings	Equipment, tools and installations	Construction in progress and advance payments	Total
Cumulative depreciation and impairment charges				
As of January 1, 2022	14.2	60.0	—	74.2
Depreciation	7.8	34.6	—	42.4
Disposals	—	(0.4)	—	(0.4)
Currency differences	—	0.1	—	0.1
As of December 31, 2022	22.0	94.3	—	116.3
As of January 1, 2023	22.0	94.3	—	116.3
Depreciation	14.4	83.3	—	97.7
Disposals	—	(1.7)	—	(1.7)
Currency differences	(0.2)	(0.3)	—	(0.5)
As of December 31, 2023	36.2	175.6	—	211.8

<i>(in millions €)</i>	Land and buildings	Equipment, tools and installations	Construction in progress and advance payments	Total
Carrying amount				
As of December 31, 2022	195.0	178.7	235.5	609.2
As of December 31, 2023	199.2	168.5	389.5	757.2

Non-Current Assets by Region

As of December 31, 2023, non-current assets comprised €158.2 million in other intangible assets, goodwill, property, plant and equipment, right-of-use assets and other assets of our subsidiaries incorporated in the United States (as of December 31, 2022: €188.0 million) as well as €511.7 million in the United Kingdom (as of December 31, 2022: nil), respectively. The remaining non-current assets of €1,469.0 million (as of December 31, 2022: €871.9 million) mainly relate to entities incorporated in Germany.

12 Financial Assets and Financial Liabilities

12.1 Capital Risk Management

Our capital management objectives are designed primarily to finance our growth strategy.

Our treasury committee reviews the total amount of cash and cash equivalents on a regular basis. As part of this review, the committee considers total cash and cash equivalents, cash outflow, currency translation differences and refinancing activities. We monitor cash using a burn rate. The cash burn rate is defined as the average monthly net cash flow from operating and investing activities during a financial year.

<i>(in millions €)</i>	December 31, 2023	December 31, 2022
Cash at banks and on hand	453.1	1,325.2
Cash equivalents	11,210.6	12,549.9
Bank deposits	2,589.5	9,401.0
Money market funds	7,446.1	3,148.9
Reverse Repo	1,175.0	—
Total	11,663.7	13,875.1

In general, the aim is to protect and maximize the financial resources available for further research and development projects.

Since December 1, 2021, we have an investment and asset management policy in place that contains policies and processes for managing cash and cash equivalents. Under this policy, our investment portfolio is to be maintained in a manner that minimizes risks to the invested capital. These risks include mainly credit risk and concentration risk. The portfolio must provide liquidity in a timely manner to accommodate operational and capital needs. The portfolio is managed by the Treasury department.

We are not subject to externally imposed capital requirements. Our capital management objectives were achieved in the years ended December 31, 2023, and 2022.

12.2 Categories of Financial Instruments

Financial Assets and Liabilities at Amortized Cost and at Fair Value through OCI and Profit or Loss

Set out below is an overview of financial assets and liabilities at amortized cost and at fair value through OCI and profit or loss, as of the dates indicated:

December 31, 2023

<i>(in millions €)</i>	Category ⁽¹⁾	Carrying amount	Level 1 (Fair value)	Level 2 (Fair value)	Level 3 (Fair value)	Total
Financial assets measured at fair value						
Money market funds	FVTPL	7,446.1	7,446.1	—	—	7,446.1
Non-listed equity investments	FVTOCI	27.1	—	—	27.1	27.1
Listed equity investments	FVTOCI	26.0	26.0	—	—	26.0
Financial assets not measured at fair value						
Trade and other receivables	AC	2,155.7	—	—	—	2,155.7
Security investments	AC	5,989.7	—	—	—	5,989.7
Other financial assets	AC	18.6	—	—	—	18.6
Bank deposits	AC	2,589.5	—	—	—	2,589.5
Reverse Repo	AC	1,175.0	—	—	—	1,175.0
Cash at banks and on hand	AC	453.1	—	—	—	453.1
Financial liabilities measured at fair value						
Foreign exchange forward contracts	FVTPL	0.4	—	0.4	—	0.4
Contingent consideration	FVTPL	38.8	—	—	38.8	38.8
Financial liabilities not measured at fair value						
Lease liabilities	n/a	216.7	—	—	—	216.7
Loans and borrowings	AC	2.3	—	—	—	2.3
Trade payables and other payables	AC	354.0	—	—	—	354.0
Other financial liabilities	AC	414.9	—	—	—	414.9

⁽¹⁾ Financial assets and liabilities categorized at amortized costs mainly correspond to fair value. Fair values are not disclosed because the book values represent a reasonable approximation of fair value. We do not make a disclosure for cash and cash equivalents, trade receivables and trade payables.

December 31, 2022

<i>(in millions €)</i>	Category ⁽¹⁾	Carrying amount	Level 1 (Fair value)	Level 2 (Fair value)	Level 3 (Fair value)	Total
Financial assets measured at fair value						
Foreign exchange forward contracts	FVTPL	183.7	—	183.7	—	183.7
Money market funds	FVTPL	3,148.9	3,148.9	—	—	3,148.9
Non-listed equity investments	FVTOCI	57.1	—	57.1	—	57.1
Listed equity investments	FVTOCI	20.0	20.0	—	—	20.0
Financial assets not measured at fair value						
Trade and other receivables	AC	7,145.6	—	—	—	7,145.6
Other financial assets	AC	8.8	—	—	—	8.8
Bank deposits	AC	9,401.0	—	—	—	9,401.0
Cash at banks and on hand	AC	1,325.2	—	—	—	1,325.2
Financial liabilities measured at fair value						
Contingent consideration	FVTPL	6.1	—	—	6.1	6.1
Financial liabilities not measured at fair value						
Lease liabilities	n/a	210.1	—	—	—	210.1
Loans and borrowings	AC	2.1	—	—	—	2.1
Trade payables and other payables	AC	204.1	—	—	—	204.1
Other financial liabilities	AC	785.1	—	—	—	785.1

⁽¹⁾ Financial assets and liabilities categorized at amortized costs mainly correspond to fair value. We do not make a disclosure for cash and cash equivalents, trade receivables and trade payables. Fair values are disclosed because the book values represent a reasonable approximation of fair value.

Equity investments designated at Fair Value through OCI

Financial investments in equity securities measured at fair value through other comprehensive income comprise the following effects:

<i>(in millions €)</i>	December 31, 2023	December 31, 2022
Net gain on equity instruments designated at fair value through other comprehensive income	3.7	10.5
Total	3.7	10.5

Measurement of fair values

The following table shows the valuation techniques used in measuring fair values for financial instruments in our consolidated statements of financial position, as well as the significant unobservable inputs used.

Type	Valuation technique	Significant unobservable inputs
------	---------------------	---------------------------------

Forward exchange contracts	Discounted cash flow using par method. Expected future cash flows based on foreign exchange forwards discounted over the respective remaining term of the contracts using the respective deposit interest rates and spot rates.	n/a
Non-listed equity investments	Quantitative and qualitative factors such as actual and forecasted results, cash position and financing round valuations.	<ul style="list-style-type: none"> – Actual and forecasted results – Cash position – Nature and pricing indication of latest financing round
Listed equity investments	Stock prices of the listed companies and applicable exchange rates, if the listing is in a foreign currency.	n/a
Money market funds	Quoted prices on an active market	n/a
Contingent consideration	Present value of expected future payments and reflecting changes in expected achievement of underlying performance parameters and compounding effects.	<ul style="list-style-type: none"> – Expected future payments – Applied cost of capital

12.3 Recurring Fair Values (Level 3)

The following table shows the recurring fair value measurement of the contingent considerations and the effect of the measurements on our consolidated statements of profit or loss for the current period.

<i>(in millions €)</i>	Contingent consideration
As of January 1, 2022	6.1
As of January 1, 2023	6.1
Purchases	31.8
Net effect on profit or loss	
Net change in fair value	0.9
As of December 31, 2023	38.8

The sensitivity of the fair values of contingent considerations in fair value level 3 to the significant, unobservable, variable input factors, with all other factors remaining constant, is shown in the following table:

Contingent consideration

Input factor	Change in assumptions	Change in fair value with increasing input factor (in millions €)	Change in fair value with decreasing input factor (in millions €)
Cash flow projections	10 %	3.4	(3.4)
Discount rate	1 %	(0.8)	0.8

The estimated fair value of non-listed equity investments would, for example, increase (decrease) if price of latest financing round were to increase (decrease) and the overall company value were higher (lower).

12.4 Financial Instruments Risk Management Objectives and Policies

Our financial liabilities mainly comprise obligations derived from license agreements, trade and other payables, lease liabilities, contingent consideration, loans and borrowings, hedging liabilities as well as other financial liabilities. The main purpose of these financial liabilities is to enable our operations. Our principal financial assets include mainly cash, security investments and trade receivables that derive directly from our operations.

We are exposed to market risk, credit risk and liquidity risk. Our Management Board oversees the management of these risks.

The treasury committee provides assurance to our Management Board that our financial risk activities are governed by appropriate policies and procedures and that financial risks are identified, measured and managed in accordance with our policies and risk objectives. The Management Board reviews and agrees policies for managing each of these risks, which are summarized below.

12.5 Market Risks

Market risks address the risks that the fair value or future cash flows of a financial instrument will fluctuate due to changes in market prices. Market risks comprise three types of risk: interest risks, foreign currency risks and other price risks. Financial instruments affected by market risks include financial assets such as security investments, trade and other receivables, cash and cash equivalents as well as financial liabilities such as trade payables and other financial liabilities. We do not consider interest risks as well as other price risks as material risks to us.

There were no material changes in the way the risks were managed and valued during the years ended December 31, 2023, and 2022. Because of the significantly higher cash balance and security investments – the market risk exposure on counterparty risk increased compared to the previous period.

Foreign Currency Risks

Foreign currency risks address the risks that the fair value or future cash flows of an exposure will fluctuate because of changes in foreign exchange rates. We are subject to currency risks, as our income and expenditures are denominated in Euro and the U.S. dollar. As such, we are exposed to exchange rate fluctuations between these currencies. Cash inflows denominated in U.S. dollar mainly result from generating proceeds under our collaboration agreements. Our commercial revenues are primarily collaboration revenues from earnings based on our partners' gross profit, which is shared under the respective collaboration agreements and represents payments we receive in U.S. dollar. Cash outflows dominated in U.S. dollar mainly result from amounts spent on research and development activities and license obligations as well as expanding our global footprint further. With the aim of preserving capital, surplus liquidity is mainly invested in domestic currency investments as exchange rate fluctuations can reduce the value of our financial positions. We limit the effects of the identified risks by means of a coordinated and consistently implemented risk strategy. Besides applying natural hedging relationships where possible, foreign exchange forward contracts are concluded, as a matter of principle, as instruments to mitigate foreign currency exchange risk associated with foreign currency-denominated payments. However, the foreign exchange forward contracts which we entered into were not designated as hedging instruments under IFRS.

The carrying amount of the monetary assets and liabilities denominated in U.S. dollar at the dates indicated are as follows:

<i>(in millions €)</i>	December 31, 2023	December 31, 2022
Cash and cash equivalents in U.S. dollar	122.6	1,487.4
Monetary assets in U.S. dollar	1,191.9	7,098.5
Monetary liabilities and provisions in U.S. dollar	567.3	1,527.8
Total	747.2	7,058.1

The following tables demonstrate the sensitivity to a reasonable, possible change in U.S. dollar exchange rates or U.S. dollar forward rates, with all other variables held constant. The impact on our profit before tax is due to changes in the fair value of monetary assets and liabilities. The exposure to foreign currency changes for all other currencies is not material.

Currency	Country	Closing rate		Average rate	
		2023	2022	2023	2022
U.S. dollar	United States	1.1050	1.0666	1.0813	1.0530

<i>(in millions €)</i>	Change in U.S. dollar rate	Effect on profit / (loss) before tax	Effect on pre-tax equity
2023	+5 %	(35.5)	(35.5)
	-5 %	39.2	39.3
2022	+5 %	(195.2)	(191.5)
	-5 %	215.7	211.7

12.6 Credit Risk Management

Credit risks address the risks that a counterparty will not meet its obligations under a financial instrument or customer contract, leading to a financial loss. We are exposed to credit risks from our operating activities, including security investments, bank deposits, reverse repos, foreign exchange transactions, trade and other receivables and cash at banks. The maximum exposure to credit risk for the components of the consolidated statements of financial position as of December 31, 2023, and December 31, 2022, are the carrying amounts as illustrated in Note 12.1 and Note 12.2.

Security Investments, Bank Deposits, Reverse Repos and Cash at banks

Our financial management is dedicated predominantly to the goal of capital preservation. Thus, all our financial activities are focused towards avoiding risks and, where they cannot be avoided, actively managing and minimizing them. Credit risks from balances with security investments, bank deposits, reverse repos and cash at banks are managed by our Treasury department in accordance with our investment and asset management policy.

Our security investments are solely invested in the highest-quality liquid assets (e.g. core European sovereign, supranational and agency bonds) and bank deposits with a maturity of more than 3 months (held at selected banks, exclusively rated as investment grade). They do not bear any currency risks or material credit risks. The bank deposits are held at selected banks, exclusively rated as investment grade. We limit our investment engagements individually and track each credit risk continuously. For reverse repos, only investment-grade counterparties qualify as our business partners and even secured investments are solely collateralized by high-quality liquid assets.

Accordingly, credit risks from these financial assets are limited. Before entering into new business relationships and during ongoing business relationships, we evaluate our business partners with regard to their individual default risk. Therefore, we do not presume an increased credit risk as of the balance sheet date and determine the impairment loss based on the upcoming twelve months.

The calculated expected credit losses were not material as of December 31, 2023, and December 31, 2022.

Trade and Other Receivables

Our exposure to credit risks of trade and other receivables is primarily related to transactions with corporate customers in the biopharma / biotech industry that operate in the United States or Germany, as well as governments which are customers, in connection with fulfilling our commercial obligations in our territories as defined in our contracts with customers. An analysis of the aging of receivables and the creditworthiness of customers is used to evaluate this risk at each reporting date. We follow risk control procedures to assess the credit quality of our customers taking into account their financial position, past experience and other factors.

As of December 31, 2023, outstanding trade and other receivables were mainly due from our collaboration partner Pfizer Besides well-established pharmaceutical companies and governmental institutions, our other customers – to a smaller extent – are medical universities, other public institutions and peers in the biopharma industry, which have good credit ratings. Due to this customer portfolio, the credit risk on trade and other receivables is generally very low. We have not incurred material bad debt expense and do not expect that this will change with respect to the trade and other receivables outstanding as of December 31, 2023.

The expected credit risk on trade and other receivables derived from applying this simplified approach in calculating expected credit losses was not material as of December 31, 2023, and December 31, 2022.

12.7 Liquidity Risk

We plan to invest heavily in R&D as we make a strong drive to build out our global development organization and diversify our therapeutic area footprint. Additionally, we plan to enhance capabilities through complementary acquisitions, technologies, infrastructure and manufacturing. Our liquidity management ensures the availability of cash and cash equivalents, short term financial instruments for operational activities and further investments through appropriate budget planning. In addition, a sufficient level of cash and cash equivalents, which are managed centrally, is always maintained to finance the operational activities.

We monitor liquidity risks using a liquidity planning tool.

Ultimately, the responsibility for liquidity risk management lies with our Management Board, which has established an appropriate approach to managing short-, medium- and long-term financing and liquidity requirements. We manage liquidity risks by holding appropriate reserves based on our COVID-19 sales, as well as by monitoring forecasted and actual cash flows and reconciling the maturity profiles of financial assets and liabilities. Significant reserves currently exist and were generated during the Covid-19 pandemic.

Risk Concentration

Concentrations arise when the number of counterparties is small or when a larger number of counterparties is engaged in similar business activities, or activities in the same geographical region, or has economic features that would cause their ability to meet contractual obligations to be affected similarly by changes in economic, political or other conditions. Concentrations indicate the relative sensitivity of our performance to developments affecting a particular industry. We only have a limited number of customers mainly comprising pharmaceutical companies and governmental institutions.

The maturity profile of our financial liabilities based on contractual undiscounted payments is summarized as follows:

Year ended December 31, 2023

<i>(in millions €)</i>	Less than 1 year	1 to 5 years	More than 5 years	Total
Loans and borrowings	—	2.3	—	2.3
Trade and other payables	354.0	—	—	354.0
Lease liabilities	34.1	136.6	73.7	244.4
Contingent consideration	—	57.5	0.3	57.8
Foreign exchange forward contracts	0.4	—	—	0.4
Other financial liabilities	414.9	—	—	414.9
Total	803.4	196.4	74.0	1,073.8

Year ended December 31, 2022

<i>(in millions €)</i>	Less than 1 year	1 to 5 years	More than 5 years	Total
Loans and borrowings	—	2.1	—	2.1
Trade and other payables	204.1	—	—	204.1
Lease liabilities	40.5	112.9	79.1	232.5
Contingent consideration	—	—	6.1	6.1
Other financial liabilities	785.1	—	—	785.1
Total	1,029.7	115.0	85.2	1,229.9

12.8 Changes in Liabilities Arising from Financing Activities

Year ended December 31, 2023

<i>(in millions €)</i>	January 1, 2023	Cash flows	New leases and disposals	Reclassifi-cation	Other	December 31, 2023
Current obligations under lease contracts	36.0	(40.3)	(0.6)	34.1	(1.1)	28.1
Non-current obligations under lease contracts	174.1	—	51.1	(34.1)	(2.5)	188.6
Loans and borrowings	2.1	0.2	—	—	—	2.3
Total	212.2	(40.1)	50.5	—	(3.6)	219.0

Year ended December 31, 2022

<i>(in millions €)</i>	January 1, 2022	Cash flows	New leases and disposals	Reclassifi-cation	Other	December 31, 2022
Current obligations under lease contracts	27.9	(41.1)	14.8	33.3	1.1	36.0
Non-current obligations under lease contracts	153.7	—	52.6	(33.3)	1.1	174.1
Loans and borrowings	119.9	(18.0)	—	—	(99.8) ⁽¹⁾	2.1
Convertible note – embedded derivative	308.7	—	—	—	(308.7) ⁽¹⁾	—
Total	610.2	(59.1)	67.4	—	(406.3)	212.2

⁽¹⁾ Related to the early redemption of our convertible note during the year ended December 31, 2023, as further described in Note 15.

13 Inventories

<i>(in millions €)</i>	December 31, 2023	December 31, 2022
Raw materials and supplies	347.5	409.7
Unfinished goods	4.0	21.0
Finished goods	6.2	8.9
Total	357.7	439.6

During the year ended December 31, 2023 expenses from inventory write-downs to net realizable value due to inventories expected to be unsellable, not fulfilling the specification defined by our quality standards, shelf-life expiry or disposals resulted in €94.5 million, compared to €484.6 million in the previous period. The inventories valued at net realizable value in our consolidated statements of financial position as of December 31, 2023, take contractual compensation payments into consideration. We have not pledged any inventories as securities for liabilities. During the years ended December 31, 2023, and 2022, costs of inventories in the amount of €354.4 million and €1,550.6 million, respectively, were recognized as cost of sales.

14 Other Non-Financial Assets

<i>(in millions €)</i>	December 31, 2023	December 31, 2022
Deferred expenses	313.2	120.0
Sales tax receivable	5.2	93.8
Prepayments related to CRO and CMO contracts	—	35.3
Other	45.9	29.3
Total	364.3	278.4
Total current	280.9	271.9
Total non-current	83.4	6.5

Deferred expenses mainly comprise prepayments for future expenses of €151.1 million (nil as of December 31, 2022) for the settlement fee of the European Commission to our collaboration partner and prepayments for our collaborations with OncoC4 Inc., Rockville, USA, €22.5 million (nil as of December 31, 2022), Ryvu Therapeutics S.A., Krakau, Poland, €15.7 million (€19.7 million as of December 31, 2022) and Medigene Immunotherapies GmbH, Planegg/Martinsried, €5.1 million (€9.4 million as of December 31, 2022). Prior year deferred expenses mainly comprise service contracts and insurance obligations.

15 Issued Capital and Reserves

As of December 31, 2023, the number of shares outstanding was 237,725,735. This amount excludes 10,826,465 shares held in treasury. For the year ended December 31, 2022, the number of shares outstanding was 243,215,169, excluding 5,337,031 shares held in treasury.

Capital Transactions During the Year Ended December 31, 2023

In March 2022, our Management Board and Supervisory Board authorized the 2022 share repurchase program of ADSs, pursuant to which we were permitted to repurchase ADSs, each representing one ordinary share, with a value of up to \$1.5 billion a two-year period, commencing on May 2, 2022. The first tranche of our 2022 share repurchase program of ADSs, with a value of up to \$1.0 billion, concluded on October 10, 2022. The second tranche with a value of up to \$0.5 billion commenced on December 7, 2022 and concluded on March 17, 2023.

The following repurchases under the programs occurred:

2022 Program first tranche (\$1.0 billion)

Period	Number of ADSs purchased	Average price paid per ADS	Net amount spent (in millions)
May 2022	917,988	\$151.76 (€143.99)	\$139.3 (€132.2)
June 2022	1,160,219	\$140.82 (€133.35)	\$163.4 (€154.7)
July 2022	519,320	\$162.03 (€159.40)	\$84.1 (€82.8)
August 2022	1,666,515	\$149.08 (€148.24)	\$248.4 (€247.0)
September 2022	2,280,988	\$135.95 (€137.66)	\$310.1 (€314.0)
October 2022	400,483	\$136.37 (€139.09)	\$54.6 (€55.7)
Total	6,945,513		\$999.9 (€986.4)

2022 Program second tranche (\$0.5 billion)

Period	Number of ADSs purchased	Average price paid per ADS	Net amount spent (in millions)
January 2023	618,355	\$142.26 (€131.12)	\$88.0 (€81.1)
February 2023	857,620	\$138.05 (€129.06)	\$118.4 (€110.7)
March 2023	745,196	\$128.49 (€121.08)	\$95.7 (€90.2)
Total	2,221,171		\$302.1 (€282.0)

In March 2023, our Management Board and Supervisory Board authorized the 2023 share repurchase program, under which we were permitted to purchase ADSs, each representing one ordinary share, with a value of up to \$0.5 billion, which started June 2, 2023 and concluded on September 18, 2023.

The following repurchases under the programs occurred:

Program 2023 (\$0.5 billion)

Period	Number of ADSs purchased	Average price paid per ADS	Net amount spent (in millions)
June 2023	1,532,685	\$108.92 (€100.45)	\$166.9 (€154.0)
July 2023	1,738,061	\$107.92 (€97.57)	\$187.6 (€169.6)
August 2023	1,261,706	\$105.07 (€95.85)	\$132.6 (€120.9)
September 2023	114,513	\$112.22 (€105.07)	\$12.9 (€12.0)
Total	4,646,965		\$500.0 (€456.5)

Capital Transactions During the Year Ended December 31, 2022

In January 2022, we announced a new research, development and commercialization collaboration with Pfizer to develop potentially the first mRNA-based vaccine for the prevention of shingles (herpes zoster virus, or HZV). In connection with this collaboration, Pfizer agreed to make an equity investment in us, acquiring 497,727 ordinary shares paying a total amount of €110.6 million. The issuance of 497,727 ordinary shares with the nominal amount of €0.5 million was registered with the commercial register (*Handelsregister*) on March 24, 2022. The equity investment, which was issued in a foreign currency, represents a derivative from the date of signing until the date of closing of the transaction. From the fair value measurement of this derivative, €43.0 million were recognized in finance income in our consolidated statements of profit or loss during the year ended December 31, 2022. At the closing date, in February 2022, this derivative and the agreed investment amount were recognized in our capital reserve and, taking an increase in share capital of €0.5 million into account, led to a net increase of the capital reserve of €67.1 million in our consolidated statements of financial position.

In March 2022, we redeemed our convertible note by exercising our early redemption option (see Note 12), which was fulfilled in April 2022, by issuing 1,744,392 ordinary shares. The nominal amount of €1.8 million was recorded in share capital and, finally, as a result of the transaction, the capital reserve increased by €233.2 million in our consolidated statements of financial position. The declaratory registration with the commercial register (*Handelsregister*) was made on May 20, 2022.

In June 2022, at the Annual General Meeting, our shareholders approved the proposed special cash dividend of €2.00 per ordinary share (including those held in the form of ADSs), which led to an aggregate payment of €484.3 million.

In November and December 2022, the ESOP 2018 and LTI-plus awards were settled by transferring ordinary shares previously held in treasury to the entitled employees and Management Board members (see Note 16).

16 Share-Based Payments

During the years ended December 31, 2023, 2022, and 2021, our share-based payment arrangements led to the following expenses:

(in millions €)	Note	Years ended December 31,		
		2023	2022	2021
Expense arising from equity-settled share-based payment arrangements		44.1	46.5	61.0
<i>Employee Stock Ownership Plan</i>	16.5	—	13.8	20.2
<i>Chief Executive Officer Grant</i>	16.4	1.2	3.1	5.9
<i>Management Board Grant⁽¹⁾</i>	16.3	3.2	4.3	2.4
<i>BioNTech 2020 Employee Equity Plan for Employees Based Outside North America</i>	16.1	36.3	25.3	32.5
<i>InstaDeep Employee Incentive Plan⁽²⁾</i>		3.4	—	—
Expense / (Income) arising from cash-settled share-based payment arrangements		7.3	61.5	32.7
<i>Employee Stock Ownership Plan</i>	16.5	(0.9)	53.4	6.3
<i>Management Board Grant⁽¹⁾</i>	16.2, 16.3	(2.4)	—	3.6
<i>BioNTech Restricted Stock Unit Plan for North America Employees</i>	16.1	10.6	8.1	22.8
Total		51.4	108.0	93.7
Cost of sales		6.5	3.0	7.0
Research and development expenses		33.4	84.6	60.5
Sales and marketing expenses		1.0	0.8	0.5
General and administrative expenses		10.5	19.6	25.7
Total		51.4	108.0	93.7

⁽¹⁾ In May 2021 and 2022, phantom options were granted under the Management Board Grant for the years 2021 and 2022 which led to a modification from an equity-settled to cash-settled share-based payment arrangement and a reclassification of €1.1 million and €3.3 million between equity and non-current other liabilities, respectively. Expenses incurred before and after the modification dates have been disclosed as equity-settled or cash-settled share-based payment arrangement, respectively. The amount includes expenses incurred with respect to a one-time signing bonus granted to Jens Holstein as of his appointment to the Management Board (see Note 21.2).

⁽²⁾ As part of the acquisition of InstaDeep (see Note 5), it was agreed to issue long-term equity awards with a total target incentive value of £15.0 million, each for options and RSUs. The allocation shall be made in a manner consistent with BioNTech's existing share-based payment arrangements. The arrangement was communicated to the employees as part of the acquisition but relates to future services. Following the rules of IFRS 2, starting with the service commencement date during the year ended December 31, 2023 and in advance of the grant date, expenses were recorded based on the estimated grant date fair values and numbers of equity instruments.

During the years ended December 31, 2023, 2022 and 2021, our share-based payment arrangements led to a cash outflow of €766.2 million, €51.8 million and €13.4 million, respectively. We expect to settle the equity-settled share-based payment arrangements of our 2020 Management Board Grant (see Note 16.3), the Chief Executive Officer Grant (see Note 16.4) and the Employee Stock Ownership Plan (see Note 16.5) on a net basis by delivering to the participant a number of ADSs equal to the net value of the exercised option rights after deduction of (i) the exercise price and (ii) the applicable wage taxes (including solidarity surcharge thereon and church tax, if applicable) and social security contributions resulting from such exercise. This reduces the dilutive impact of the respective rights compared to an all-equity settlement. If all of the equity-settled rights outstanding as of December 31, 2023, were to be exercised accordingly, the cash outflow to the tax authority in 2024 would amount to approximately €213.0 million (based on the share price as of December 31, 2023).

16.1 BioNTech Employee Equity Plan

BioNTech 2020 Employee Equity Plan for Employees Based Outside North America (Equity-Settled)

Description of Share-Based Payments

In December 2020, we approved the BioNTech 2020 Employee Equity Plan for employees based outside North America, or the European Plan. Under the European Plan, Restricted Stock Units, or RSUs, are offered to our employees.

Award agreements were entered as of the respective grant dates in February 2021 (LTI 2020 and LTI-plus program), January 2022 (LTI 2021 program) and December 2022 (LTI 2022 program). RSUs issued under the LTI 2020, LTI 2021 and LTI 2022 programs vest annually in equal installments over respective waiting periods of four years, commencing in December 2020, December 2021 and December 2022, respectively. RSUs issued under the LTI-plus program vested annually in equal installments over the waiting period of two years, which elapsed in December 2022. Hence, during the year ended December 31, 2022, the LTI-plus awards were settled by transferring shares previously held in treasury, see Note 15. All programs were classified as equity-settled as we have the ability to determine the method of settlement.

Measurement of Fair Values

The fair values of the awards issued under the European Plan were based upon the price of our ADSs representing ordinary shares at the grant date.

Reconciliation of Outstanding Share-Options

	LTI-plus program	LTI 2020 program	LTI 2021 program	LTI 2022 program
As of January 1, 2022	372,011	242,416	110,036	—
Forfeited / Modified	(7,932)	(7,111)	(5,428)	—
Granted / Allocated	—	—	—	396,110
Settled ⁽¹⁾	(364,079)	—	—	—
As of December 31, 2022	—	235,305	104,608	396,110
As of January 1, 2023	—	235,305	104,608	396,110
Forfeited / Modified	—	(4,400)	(3,497)	(16,141)
As of December 31, 2023	—	230,905	101,111	379,969
<i>thereof vested</i>	—	175,523	51,905	96,466
<i>thereof unvested</i>	—	55,382	49,206	283,503

⁽¹⁾ The closing price of an American Depositary Share of BioNTech on Nasdaq on December 15, 2022, the settlement date, converted from USD to Euro using the exchange rate published by the German Central Bank (Deutsche Bundesbank) on the same day was €171.40.

Inputs Used in Measurement of the Fair Values at Grant Dates

	LTI-plus program	LTI 2020 program	LTI 2021 program	LTI 2022 program
Weighted average fair value	87.60	92.21	203.22	165.03
Waiting period (in years)	2.0	4.0	4.0	4.0

BioNTech 2020 Restricted Stock Unit Plan for North America Employees (Cash-Settled)

Description of Share-Based Payments

In December 2020, we approved the BioNTech 2020 Restricted Stock Unit Plan for North America Employees, or the North American Plan. Under the North American Plan, RSUs are offered to our employees. These RSUs vest over four years, with 25% vesting one year after the service commencement date and the remainder vesting in equal quarterly installments thereafter. The first awards under the North American Plan were granted in February 2021. The service date for these awards is the date as of which the employee became employed by BioNTech US. During the years ended December 31, 2023, and 2022, further awards were granted under the North American Plan, which included awards granted

to new-hire employees and ongoing, recurring awards to existing employees on the approximate anniversary of each employee's start date of employment with BioNTech US. As these RSUs are intended to be cash-settled upon vesting, the awards were defined as a cash-settled share-based payment arrangement. During the years ended December 31, 2023, 2022 and 2021, the exercise of RSUs resulted in a cash outflow of €10.0 million, €9.4 million and €10.1 million, respectively.

As of December 31, 2023, the liability related to these awards amounted to €14.4 million (€13.4 million as of December 31, 2022).

16.2 Management Board Grant – Short-Term Incentive (Cash-Settled)

Management Board's service agreements also include a short-term incentive compensation component, which is an annual performance-related bonus for the years of their respective service periods.

50% of those yearly awards are paid out one year after the achievement of the performance targets for the respective bonus year has been determined, subject to an adjustment relative to the performance of the price of the American Depositary Shares representing our ordinary shares during that year (second installment). The second installments represent cash-settled share-based payment arrangements. The fair values of the liabilities are recognized over the awards' vesting periods beginning when entering or renewing service agreements, i.e., the service commencement date, until each separate determination date and are remeasured until the settlement date. As of December 31, 2023, the liability related to these awards amounted to €2.1 million (€2.3 million as of December 31, 2022).

16.3 Management Board Grant Long-Term Incentive (Partly Equity-Settled, Partly Cash-Settled)

Description of Share-Based Payments

Our Management Board's service agreements provide for long-term incentive compensation (Management Board Grant - LTI) through an annual grant of options to acquire BioNTech shares during their respective service periods. The options granted each year are subject to the terms and conditions of the respective authorizations of the Annual General Meeting creating our Employee Stock Ownership Plan (ESOP) and the applicable option agreements thereunder.

The options vest annually in equal installments over four years commencing on the first anniversary of the allocation date and are exercisable four years after the allocation date. The vested options can only be exercised if each of the following performance criteria has been achieved: (i) at the time of exercise, the current price is equal to or greater than the threshold amount (that is, the exercise price, provided that such amount increases by seven percentage points on each anniversary of the allocation date); (ii) at the time of exercise, the current price is at least equal to the target price (that is, (a) for the twelve-month period starting on the fourth anniversary of the allocation date, \$8.5 billion divided by the total number of the ordinary shares outstanding immediately following the initial public offering (other than ordinary shares owned by BioNTech), and (b) for each twelve-month period starting on the fifth or subsequent anniversary of the allocation date, 107% of the target share price applicable for the prior twelve-month period); and (iii) the closing price for the fifth trading day prior to the start of the relevant exercise window is higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index or a comparable successor index as of such time is higher than such index was as of the last trading day before the allocation date. Following the expiry of the waiting period, option rights may be exercised during the exercise windows as set out in the ESOP agreement. The option rights can be exercised up to ten years after the allocation date. If they have not been exercised by that date, they will be forfeited without compensation.

The right to receive options generally represents an equity-settled share-based payment arrangement. The allocation of the number of issued options in 2020 occurred in February 2020. In May 2021 and May 2022, the Management Board received phantom options equivalent to the number of options the Management Board members would have been entitled to receive for 2021 and 2022, which led to a modification from equity-settled to cash-settled share-based payment arrangement and a reclassification of €1.1 million and €3.3 million between equity and non-current other liabilities as of the respective allocation dates. During 2023, options were granted in May 2023.

Measurement of Fair Values

A Monte-Carlo simulation model has been used to measure the fair values at the (estimated) allocation dates of the Management Board Grant. This model incorporates the impact of the performance criteria regarding share price and index

development described above. The parameters used for measuring the fair values as of the respective (estimated) allocation dates were as follows:

	Allocation date February 2020	Allocation date May 12, 2021 ⁽¹⁾	Allocation date May 17, 2021 ⁽¹⁾	Allocation date May 2022 ⁽¹⁾
Weighted average fair value	€10.83	€29.05	€27.64	€38.88
Weighted average share price	€28.20	€168.44	€179.46	€147.84
Exercise price ⁽²⁾	€28.32	€167.63	€169.08	€137.65
Expected volatility	36.6 %	49.7 %	49.7 %	49.7 %
Expected life (years)	4.8	4.6	4.6	5.8
Risk-free interest rate	1.6 %	3.9 %	3.9 %	3.9 %

⁽¹⁾ Classified as cash-settled share-based payment arrangement; all other share-based payment arrangements are classified as equity-settled.

⁽²⁾ The share options allocated as of February 2020 and May 2023 as well as the phantom share options allocated as of May 2021 and 2022 are subject to an effective exercise price cap.

	Allocation date May 2023	Estimated allocation date 2024	Estimated allocation date 2025	Estimated allocation date 2026
Weighted average fair value ⁽¹⁾	€46.29	€43.67	€39.97	€32.86
Weighted average share price ⁽¹⁾	€98.93	€95.51	€95.51	€95.51
Exercise price ⁽¹⁾	€105.42	€96.82	€99.74	€105.13
Expected volatility	47.2 %	47.7 %	43.0 %	36.8 %
Expected life (years) ⁽¹⁾	5.8	5.8	5.8	5.8
Risk-free interest rate	3.7 %	3.9 %	3.9 %	3.9 %

⁽¹⁾ Valuation parameter for estimated allocation dates derived from the Monte-Carlo simulation model.

For the awards with estimated allocation dates, the exercise prices of options expected to be allocated have been derived from the Monte-Carlo simulation model. Those will be adjusted until the actual allocation has occurred and the exercise price has ultimately been determined.

All options are subject to an effective exercise price cap, which means that the exercise price shall be adjusted to ensure that the current price of an ADS as of the exercise date does not exceed 800% of the exercise price. With respect to the LTI 2020 agreement, the maximum economic benefit receivable in respect of any exercised option is capped at \$246.24, with the effective exercise price being capped at a Euro amount equivalent to \$30.78. With respect to the phantom share options issued under the LTI 2021 and 2022 as well as the options issued under the LTI 2023 programs, the maximum compensation that the Management Board members are entitled to receive under such programs, together with other compensation components received by each such board member in the respective grant year, shall not exceed €20.0 million for Ugur Sahin as Chief Executive Officer (CEO) and €10.0 million for all other Management Board members.

Expected volatility was based on an evaluation of the historical volatilities of comparable companies over the historical period commensurate with the expected option term. The expected term was based on general option holder behavior for employee options.

Reconciliation of Outstanding Share-Options

The (phantom) share options allocated and expected to be allocated to our Management Board as of December 31, 2023, are presented in the table below.

	Allocation date February 2020	Allocation date May 12, 2021 ⁽¹⁾	Allocation date May 17, 2021 ⁽¹⁾	Allocation date May 2022 ⁽¹⁾
(Phantom) share options outstanding	248,096	45,279	6,463	86,118
<i>thereof allocated and vested but subject to performance and waiting requirements</i>	186,072	22,640	3,232	21,531
<i>thereof allocated and unvested</i>	62,024	22,639	3,231	64,587
Weighted average exercise price (€)	28.32	167.63	169.08	137.65

⁽¹⁾ Classified as cash-settled share-based payment arrangement; all other share-based payment arrangements are classified as equity-settled.

	Allocation date May 2023 ⁽¹⁾	Estimated allocation date 2024 ⁽¹⁾	Estimated allocation date 2025 ⁽¹⁾	Estimated allocation date 2026 ⁽¹⁾
Share options outstanding / expected to be allocated	130,586	164,148	118,312	93,561
<i>thereof allocated and unvested</i>	130,586	—	—	—
Weighted average exercise price (€)	105.42	96.82	99.74	105.13

⁽¹⁾ Valuation parameter derived from the Monte-Carlo simulation model.

For the awards with estimated allocation dates, the numbers of options expected to be allocated have been derived from a Monte-Carlo simulation model. Those will be adjusted until the actual allocation has occurred and the number of options granted has ultimately been determined.

As of December 31, 2023, the share options allocated and expected to be allocated under our equity-settled share-based payment arrangements had a remaining weighted average expected life of 4.1 years (as of December 31, 2022: 4.0 years).

As of December 31, 2023, the liability related to the phantom option awards amounted to €3.6 million (€5.6 million as of December 31, 2022).

16.4 Chief Executive Officer Grant (Equity-Settled)

Description of Share-Based Payments

In September 2019, we granted Ugur Sahin an option to purchase 4,374,963 of our ordinary shares, subject to Sahin's continuous employment with us. The options' exercise price per share is the Euro translation of the public offering price from our initial public offering, €13.60 (\$15.00), which is subject to the effective exercise price cap and the maximum cap mechanism. Under the exercise price cap the exercise price shall be adjusted to ensure that the current price of an ADS as of the exercise date does not exceed 800% of the exercise price. Under the maximum cap mechanism the maximum economic benefit receivable in respect of any exercised option is capped at \$240.00 with the effective exercise price being capped at a Euro amount equivalent to \$30.00

The options vest annually in equal installments after four years commencing on the first anniversary of the initial public offering and have a waiting period of four years after the initial public offering. The vested option rights can only be exercised if and to the extent that each of the following performance criteria has been achieved: (i) at the time of exercise, the current price is equal to or greater than the threshold amount (that is, the exercise price, provided that such amount increases by seven percentage points on each anniversary of the allocation date); (ii) at the time of exercise, the current price is at least equal to the target price (that is, (a) for the twelve-month period starting on the fourth anniversary of the allocation date, \$8.5 billion divided by the total number of the shares outstanding immediately following the initial public offering (other than shares owned by us), and (b) for each twelve-month period starting on the fifth or subsequent

anniversary of the allocation date, 107% of the target share price applicable for the prior twelve-month period); and (iii) the closing price for the fifth trading day prior to the start of the relevant exercise window is higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index or a comparable successor index as of such time is higher than such index was as of the last trading day before the allocation date. Following the expiry of the waiting period, option rights may be exercised during the exercise windows as defined by our ESOP. The option rights can be exercised up to ten years after the allocation date. If they have not been exercised by that date, they will be forfeited without compensation.

Measurement of Fair Values

A Monte-Carlo simulation model has been used to measure the fair value at the grant date of the Chief Executive Officer Grant. This model incorporates the impact of the performance criteria regarding share price and index development described above in the calculation of the award's fair value at the grant date. The inputs used in the measurement of the fair value at the grant date of the Chief Executive Officer Grant were as follows:

	Grant date October 9, 2019
Weighted average fair value	€5.63
Weighted average share price	€13.60
Exercise price	€13.60
Expected volatility	41.4 %
Expected life (years)	5.4
Risk-free interest rate	1.5 %

Expected volatility was based on an evaluation of the historical volatilities of comparable companies over the historical period commensurate with the expected term. The expected term was based on general option holder behavior for employee options.

Reconciliation of Outstanding Share-Options

On October 9, 2023, with the final installment vesting, all 4,374,963 options became exercisable under the rules of the ESOP and the ESOP agreement. During the year ended December 31, 2023, no options were exercised.

As of December 31, 2023, the share options outstanding had a remaining weighted average expected life of 1.1 years (as of December 31, 2022: 2.1 years).

16.5 Employee Stock Ownership Plan (Partly Equity-Settled, Partly Cash-Settled)

Description of Share-Based Payments

Based on an authorization of the general meeting on August 18, 2017, we established a share option program under which we granted selected employees options to receive our shares. The program is designed as an Employee Stock Ownership Plan, or ESOP. We offered participants a certain number of option rights by their explicit acceptance of an option rights agreement. The exercise of option rights in accordance with the agreement gives the participants the right to obtain shares against payment of the exercise price. With respect to the Management Board members serving at the time of allocation, the options are subject to the effective exercise price cap and maximum cap mechanisms. Under the exercise price cap, the exercise price shall be adjusted to ensure that the current price of an ADS as of the exercise date does not exceed 800% of the exercise price. Under the maximum cap mechanism, the maximum economic benefit receivable in respect of any exercised option, is capped at \$240, with the effective exercise price being capped at a Euro amount equivalent to \$30.00. Under the ESOP, the option rights (other than Özlem Türeçli's, and Ryan Richardson's options) fully vest after four years and can be exercised if: (i) the waiting period of four years has elapsed; and (ii) at the time of exercise, the average closing price of the shares of the Company or the average closing price of the right or certificate to be converted into an amount per share on the previous ten trading days preceding the exercise of the option right exceeds the strike price by a minimum of 32%, with this percentage increasing by eight percentage points as of the fifth anniversary of the respective issue date and as of each subsequent anniversary date. Following the expiry of the waiting period, option rights may be exercised within a period of four weeks from the date of the Annual General Meeting or the publication of the annual financial statements, the semi-annual report or our most recent quarterly report or interim report (exercise windows).

The option rights can be exercised up to eight years after the allocation date. If they have not been exercised by that date, they will be forfeited without compensation.

By way of a shareholders' resolution of the general meeting on August 19, 2019, the authorization to issue such option rights was amended such that, in order for the options to be exercisable, the average closing price of the Company's shares or the average closing price of the right or certificate to be converted into an amount per share on the ten trading days immediately preceding the exercise must exceed the strike price by a minimum of 28%, with this percentage increasing by seven percentage points as of the fifth anniversary of the issue date and as of each subsequent anniversary date. Furthermore, in addition to the aforementioned requirements, the exercise is only possible if the share price (calculated by reference to the price of the ordinary share underlying the ADS) has performed similar to or better than the Nasdaq Biotechnology Index. The changes made do not affect option rights already issued.

Measurement of Fair Values

The fair value of the ESOP has been measured using a binomial model. Service conditions attached to the arrangement were not taken into account in measuring the fair value.

The share options can only be exercised by the grantee if the price of the share is equal or greater to the threshold amount as defined in the arrangement. Moreover, the option rights can only be exercised if the IPO has occurred. Both conditions have been incorporated into the fair value at the grant date.

The inputs used in the measurement of the fair values at the grant date of the ESOP were as follows:

	Grant date November 15, 2018	Grant dates between February 21 and April 3, 2019	Grant dates between April 29 and May 31, 2019	Grant date December 1, 2019
Weighted average fair value	€7.41	€6.93	€7.04	€9.49
Weighted average share price	€14.40	€15.72	€16.03	€19.84
Exercise price ⁽¹⁾	€10.14	€15.03	€15.39	€15.82
Expected volatility	46.0 %	46.0 %	46.0 %	46.0 %
Expected life (years)	5.8	6.0	6.0	5.5
Risk-free interest rate	0.1 %	0.1 %	0.1 %	0.1 %

⁽¹⁾ With respect to the Management Board members appointed as such at the time the options were granted, the options are subject to the effective exercise price cap as well as the maximum cap mechanism.

Expected volatility has been based on an evaluation of the historical and the implied volatilities of comparable companies over the historical period commensurate with the expected term. The expected term has been based on general option holder behavior for employee options.

Reconciliation of Outstanding Share-Options (Equity-Settled)

Set out below is an overview of changes to share options outstanding and number of ordinary shares underlying these options that occurred during the periods indicated:

	Share options outstanding	Number of ordinary shares underlying options	Weighted average exercise price (€) ⁽¹⁾
As of January 1, 2022	642,007	11,556,124	10.23
Modified ⁽²⁾	(1,040)	(18,720)	10.14
Exercised ⁽³⁾	(583,383)	(10,500,890)	10.14
As of December 31, 2022	57,584	1,036,514	11.10
As of January 1, 2023	57,584	1,036,514	11.10
Exercised ⁽³⁾	(39,785)	(716,121)	11.04
As of December 31, 2023	17,799	320,393	11.24
<i>thereof vested</i>	<i>17,799</i>	<i>320,393</i>	<i>11.24</i>
<i>thereof unvested</i>	<i>—</i>	<i>—</i>	<i>—</i>

⁽¹⁾ With respect to the Management Board members appointed as such at the time the options were granted, the options are subject to the effective exercise price cap as well as the maximum cap mechanism.

⁽²⁾ Rights have been modified to cash-settled rights, all other terms remained unchanged.

⁽³⁾ The average closing price of an American Depositary Share of BioNTech on Nasdaq weighted over the various dates immediately preceding the settlement dates, converted from USD to Euro using the exchange rate published by the German Central Bank (Deutsche Bundesbank) on the same days was €96.49 and €160.44 for all settlements during the years ended December 31, 2023 and 2022, respectively.

In September 2022, the Supervisory Board determined the ESOP settlement by the delivery of treasury shares (in the form of ADSs) equal to the net value of the exercised option rights after deduction of (i) the exercise price and (ii) the applicable wage taxes (including solidarity surcharge thereon and church tax, if applicable) and social security contributions resulting from such exercise. The settlement was applied during the exercise windows in 2022 and 2023. The applicable wage taxes (including solidarity surcharge thereon and church tax, if applicable) and social security contributions resulting from and withheld upon the exercise amounted to €724.0 million and were paid in January 2023 in cash directly to the respective authorities. The settlement mechanism decision did not change the rights as such, neither did it change the classification as equity-settled option rights.

As of December 31, 2023, the share options outstanding under our equity-settled share-based payment arrangements had a remaining weighted average expected life of 0.8 years (as of December 31, 2022: 1.7 years).

Development of Share-Options (Cash-Settled)

Phantom options which were granted under the ESOP mainly during the year ended December 31, 2022 each give the participants the right to receive a cash payment equal to the difference between an exercise closing price (average closing price of an American Depositary Share of BioNTech on Nasdaq over the last ten trading days preceding the exercise date) and the exercise price. The majority of options have an exercise price of €10.14. During the years ended December 31, 2023, and 2022, 52,100 and 289,168 cash-settled phantom option rights were exercised and resulted in a cash outflow of €4.5 million and €42.2 million, respectively. The average closing prices (10-day averages) of an American Depositary Share of BioNTech on Nasdaq weighted over the various settlement dates converted from USD to Euro using the exchange rate published by the German Central Bank (*Deutsche Bundesbank*) on the same days was €96.25 and €155.39. As of December 31, 2023, 109,651 cash-settled option rights remained outstanding. As of December 31, 2023, the liability related to cash-settled share-based payment option rights amounted to €8.5 million (€14.5 million as of December 31, 2022), of which €8.3 million (€11.2 million as of December 31, 2022) related to rights already vested (partly subject to performance and waiting requirements). The liability is based on the fair value of the respective rights. The fair value is measured using a binomial model consistent with the grant date fair value measurement of the equity-based option rights described above, which is updated on every reporting date.

17 Provisions

<i>(in millions €)</i>	December 31, 2023	December 31, 2022
Contractual disputes	118.2	88.9
Obligations from onerous CMO contracts	80.2	235.5
Other	79.7	51.4
Total	278.1	375.8
Total current	269.3	367.2
Total non-current	8.8	8.6

As of December 31, 2023, our current provisions included €118.2 million in contractual disputes mainly related to purported obligations arising out of certain contractual disputes unrelated to the below-mentioned patent proceedings (€88.9 million as of December 31, 2022). Acknowledging an increase in obligations identified as contractual disputes, the change of €29.3 million compared to the previous period related mainly to additions.

As of December 31, 2023, our current provisions included €80.2 million (€235.5 million as of December 31, 2022) of obligations for production capacities derived from contracts with Contract Manufacturing Organizations, or CMOs, that became redundant. The effects were driven by reducing production capacities as well as further fostering the global production network with our collaboration partners during the year ended December 31, 2023. The related expenses were recognized in cost of sales in our consolidated statements of profit or loss. The change of €(155.3) million compared to the previous period related to addition (€45.1 million), to release (€126.0 million) and usage (€74.5 million).

As of December 31, 2023, our current provisions included €79.7 million in other obligations mainly comprising inventor remunerations as well as customs and duties (€51.4 million as of December 31, 2022, mainly comprising inventor remunerations as well as customs and duties). The change of €28.3 million compared to the previous period related mainly to additions.

18 Contingencies and other financial commitments

Contingencies

Our contingencies include, but are not limited to, intellectual property disputes and product liability and other product-related litigation. From time to time, in the normal course and conduct of our business, we may be involved in discussions with third parties about considering, for example, the use and/or remuneration for use of such third party's intellectual property. As of December 31, 2023, none of such intellectual property-related considerations that we have been notified of, and for which potential claims could be brought against us or our subsidiaries in the future, fulfill the criteria for recording a provision. We are subject to an increasing number of product liability claims. Such claims often involve highly complex issues related to medical causation, correctness and completeness of product information (Summary of Product Characteristics/package leaflet) as well as label warnings and reliance thereon, scientific evidence and findings, actual and provable injury, and other matters. These complexities vary from matter to matter. As of December 31, 2023, none of these claims fulfill the criteria for recording a provision. Substantially all of our contingencies are subject to significant uncertainties and, therefore, determining the likelihood of a loss and/or the measurement of any loss can be complex. Consequently, we are unable to estimate the range of reasonably possible loss. Our assessments, which result from a complex series of judgments about future events and uncertainties, are based on estimates and assumptions that have been deemed reasonable by management, but that may prove to be incomplete or inaccurate, and unanticipated events and circumstances may occur that might cause us to change those estimates and assumptions. We currently do not believe that any of these matters will have a material adverse effect on our financial position, and will continue to monitor the status of these and other claims that may arise. However, we could incur judgments, enter into settlements or revise our expectations regarding the outcome of matters, which could have a material adverse effect on our results of operations and/or our cash flows in the period in which the amounts are accrued or paid. We will continue to evaluate whether, if circumstances were to change in the future, the recording of a provision may be needed and whether potential indemnification entitlements exist against any such claim.

Certain pending matters to which we are a party are discussed below.

Alnylam Proceedings

In March 2022, Alnylam Pharmaceuticals, Inc., or Alnylam, filed a lawsuit against Pfizer and Pharmacia & Upjohn Co. LLC in the U.S. District Court for the District of Delaware alleging that an existing patent owned by Alnylam, U.S. Patent No. 11,246,933, or the '933 Patent, is infringed by the cationic lipid used in *Comirnaty*, and seeking monetary relief, which is not specified in their filings. We filed a counterclaim to become party to the Alnylam proceeding, and in June 2022, Alnylam added to its claims allegations that we induced infringement of the '933 Patent. Additionally, in July 2022, Alnylam filed a lawsuit against us, our wholly owned subsidiary, BioNTech Manufacturing GmbH, Pfizer and Pharmacia & Upjohn Co. LLC in the U.S. District Court for the District of Delaware alleging that we also induced infringement of a newly issued patent, U.S. Patent No. 11,382,979, or the '979 Patent, which is a continuation of the '933 Patent. The two lawsuits were consolidated on July 28, 2022. In May 2023, Alnylam filed a third lawsuit against Pfizer Inc. and Pharmacia & Upjohn Co. LLC in the U.S. District Court for the District of Delaware alleging infringement of U.S. Patent Nos. 11,633,479; 11,633,480; 11,612,657; and 11,590,229, all of which are continuations of the '933 Patent. We filed a counterclaim to become party to the new proceeding, and in July 2023, Alnylam added to its claims allegations that we induced infringement of the four new patents. All of the proceedings have been consolidated and are currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the proceedings mentioned above. However, our analysis of Alnylam's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

CureVac Proceedings

Germany

Infringement Proceedings – EP'122, DE'961, DE'974, DE'575, and EP'668

In July 2022, CureVac AG, or CureVac, filed a lawsuit against us and our wholly owned subsidiaries, BioNTech Manufacturing GmbH and BioNTech Manufacturing Marburg GmbH, in the Düsseldorf Regional Court, alleging *Comirnaty*'s infringement of one European patent, EP1857122B1, or the EP'122 Patent, and three Utility Models DE202015009961U1, DE202015009974U1, and DE202021003575U1. In August 2022, CureVac added European Patent EP3708668B1, or the EP'668 Patent, to its German lawsuit.

On August 15, 2023, the Düsseldorf Regional Court held a hearing on infringement with respect to all five IP rights. At the hearing, the Court suspended its infringement ruling with respect to EP'122 until December 28, 2023. On September 28, 2023, the Court issued orders suspending its infringement rulings with respect to the remaining four IP rights (DE'961, DE'974, DE'575, and EP'668) pending validity decisions in the DE'961, DE'974, and DE'575 cancellation proceedings before the German Patent and Trademark Office and in the EP'668 opposition proceedings before the Opposition Division of the European Patent Office. In the September 28th orders, the Court explained that it was suspending its infringement rulings until validity decisions are reached, while contemporaneously noting concerns regarding the validity of DE'961, DE'974, DE'575, and EP'668. On December 28, 2023, the Düsseldorf Regional Court stayed the infringement proceedings as to EP'122 until a final appellate decision is rendered as to the validity of EP 122 by the Federal Court of Justice.

Infringement Proceedings – EP'755, DE'123, and DE'130

In July 2023, CureVac SE filed a second lawsuit against us and our wholly owned subsidiaries, BioNTech Manufacturing GmbH and BioNTech Manufacturing Marburg GmbH, in the Düsseldorf Regional Court, alleging *Comirnaty*'s infringement of one European patent, EP4023755B1, or the EP'755 Patent, and two Utility Models DE202021004123U1, and DE202021004130U1.

Nullity Proceedings – EP'122

In September 2022, we filed a nullity action in the Federal Patent Court of Germany seeking a declaration that the EP'122 Patent is invalid. In April 2023, the Federal Patent Court of Germany issued a preliminary opinion in the EP'122 nullity action in support of the validity of the EP'122 Patent. The preliminary opinion did not address any infringement of the EP'122 Patent. The preliminary opinion is a preliminary assessment by the court of the merits of a claim, and is non-binding. On December 19, 2023, the Federal Patent Court held an oral hearing, after which it nullified EP'122.

Cancellation Proceedings – DE'961, DE'974, and DE'575

In November 2022, we filed cancellation actions seeking the cancellation of the three German Utility Models in the German Patent and Trademark Office. On December 27, 2023, the German Patent Office issued a preliminary opinion that DE'974 is likely to be cancelled based on invalidity pursuant to para. 1 (2) no. 5 Utility Model Act.

United States

In July 2022, we and Pfizer filed a complaint for a declaratory judgment in the U.S. District Court for the District of Massachusetts, seeking a judgment of non-infringement by *Comirnaty* of U.S. Patent Nos. 11,135,312, 11,149,278 and 11,241,493. In May 2023, the action in the U.S. District Court for the District of Massachusetts was transferred to the U.S. District Court for the Eastern District of Virginia, where CureVac filed counterclaims asserting infringement of six additional U.S. patents, U.S. Patent Nos. 10,760,070; 11,286,492; 11,345,920; 11,471,525; 11,576,966; and 11,596,686. In July 2023, CureVac filed amended counterclaims to assert an additional U.S. patent, U.S. Patent No. 11,667,910.

United Kingdom

In September 2022, we and Pfizer filed a declaration of non-infringement and revocation action against the EP'122 Patent and the EP'668 Patent in the Business and Property Courts of England and Wales. In October 2022, CureVac responded by filing a counterclaim alleging infringement of the EP'122 and EP'668 patents in the Business And Property Courts of England and Wales. On December 18, 2023, we amended our pleadings to further allege non-infringement and invalidity against EP'755.

All of the above proceedings are currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and utility models and intend to vigorously defend ourselves in the proceedings mentioned above. However, our analysis of CureVac's claims is ongoing and complex, and we believe the ultimate outcomes remain substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

Moderna Proceedings

Germany

Infringement Proceedings – EP'949 and EP'565

In August 2022, Moderna filed a lawsuit against us and Pfizer and our wholly owned subsidiaries, BioNTech Manufacturing GmbH, BioNTech Europe GmbH and BioNTech Manufacturing Marburg GmbH, Pfizer Manufacturing Belgium NV, Pfizer Ireland Pharmaceuticals and Pfizer Inc. in the Düsseldorf Regional Court alleging *Comirnaty*'s infringement of two European Patents, 3590949B1, or the EP'949 Patent, and 3718565B1, or the EP'565 Patent. On November 7, 2023, the European Patent Office ("EPO") Opposition Division revoked EP'565 after a one-day oral hearing. The Opposition Division issued a preliminary opinion on December 8, 2023 noting that it believes EP'949 is likely invalid. As a result of these EPO proceedings, the Düsseldorf Regional Court postponed its hearing on infringement, originally scheduled for December 12, 2023, to January 21, 2025.

United Kingdom

In August 2022, Moderna filed a lawsuit asserting *Comirnaty*'s infringement of the EP'949 Patent and EP'565 Patent against us and our wholly owned subsidiaries, BioNTech Manufacturing GmbH, BioNTech Europe GmbH and BioNTech Manufacturing Marburg GmbH, Pfizer Limited, Pfizer Manufacturing Belgium NV and Pfizer Inc. in the Business and Property Courts of England and Wales. In September 2022, we and Pfizer filed a revocation action in the Business and Property Courts of England and Wales requesting revocation of the EP'949 Patent and EP'565 Patent.

United States

U.S. District Court Litigation

In August 2022, Moderna filed a lawsuit in the United States District Court for the District of Massachusetts against us and our wholly owned subsidiaries BioNTech Manufacturing GmbH and BioNTech US Inc. and Pfizer Inc. alleging *Comirnaty*'s infringement of U.S. Patent Nos. 10,898,574, 10,702,600 and 10,933,127 and seeking monetary relief.

Inter Partes Review

In August 2023, Pfizer and we filed petitions seeking inter partes review of U.S. Patent Nos. 10,702,600 and 10,933,127 before the United States Patent Trial and Appeal Board.

Netherlands

In September 2022, Moderna filed a lawsuit against us and our wholly owned subsidiary BioNTech Manufacturing GmbH and Pfizer B.V., Pfizer Export B.V., C.P. Pharmaceuticals International C.V. and Pfizer Inc. in the District Court of The Hague alleging Comirnaty's infringement of the EP '949 Patent and the EP '565 Patent. The District Court of the Hague held a hearing on October 6, 2023 on infringement and validity with respect to the EP '949 Patent. On December 6, 2023, the Court found EP'949 to be invalid. The EP'565 case has been stayed pending Moderna's appeal of the Opposition Division's revocation of EP'565.

Ireland

In May 2023, Moderna filed a lawsuit against us and our wholly owned subsidiary BioNTech Manufacturing GmbH, Pfizer Inc., Pfizer Healthcare Ireland, Pfizer Ireland Pharmaceuticals, and C.P. Pharmaceuticals International C.V. alleging Comirnaty's infringement of the EP'949 Patent and EP'565 Patent in the High Court of Ireland.

Belgium

In May 2023, Moderna filed a lawsuit against us, our wholly owned subsidiary BioNTech Manufacturing GmbH, Pfizer Inc. and Pfizer Manufacturing Belgium alleging Comirnaty's infringement of the EP'949 Patent and the EP'565 Patent in the Brussels Dutch-speaking Enterprise Court.

All of the above proceedings are currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the proceedings mentioned above. However, our analysis of Moderna's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

Arbutus and Genevant Proceedings

In April 2023, Arbutus Biopharma Corp., or Arbutus, and Genevant Sciences GmbH, or Genevant, filed a lawsuit against Pfizer and us in the U.S. District Court for the District of New Jersey alleging that Pfizer and we have infringed the following patents owned by Arbutus: U.S. Patent Nos. 9,504,651; 8,492,359; 11,141,378; 11,298,320; and 11,318,098, through the use of Genevant's lipid nanoparticle technology and methods for producing such lipids in Comirnaty, and seeking monetary relief. This proceeding is currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the lawsuit mentioned above. However, our analysis of Arbutus and Genevant's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

Promosome Proceedings

In June 2023, Promosome LLC filed a lawsuit against Pfizer, us, and BioNTech Manufacturing GmbH in the U.S. District Court for the Southern District of California alleging that Pfizer and our Comirnaty vaccine has infringed U.S. Patent No. 8,853,179, and seeking monetary relief. On October 4, 2023, the parties filed a joint stipulation of dismissal, dismissing the lawsuit with prejudice. As part of this stipulation of dismissal, Promosome agreed to a covenant not to assert U.S. Patent No. 8,853,179 against Pfizer and us or any of their products, including Comirnaty. This matter is considered closed.

Other financial commitments

The other financial commitments were as follows:

<i>(in millions €)</i>	December 31, 2023	December 31, 2022
Commitments under purchase agreements for property, plant and equipment	154.4	105.2
Contractual obligation to acquire intangible assets	1,721.1	—
Total	1,875.5	105.2

Contractual obligations to acquire intangible assets exist in connection with in-licensing and research and development collaborations. We have entered into obligations to make milestone payments once specific targets have been reached. Provided that all of the milestone events are achieved, we would be obligated to pay up to €1,721.1 million as of December 31, 2023 (nil as of December 31, 2022) in connection with the acquisition of intangible assets. The amounts shown represent the maximum payments to be made, and it is unlikely that they will all fall due. The amounts and the dates of the actual payments may both vary considerably from those stated in the table, since the achievement of the conditions for payment is possible but uncertain. Other financial obligations from possible future sales-based milestone and license payments were not included in the table above.

The expected maturities of payment obligations under purchase agreements for property, plant and equipment and contractual obligations to acquire intangible assets are as follows:

Year ended December 31, 2023

<i>(in millions €)</i>	Less than 1 year	1 to 5 years	More than 5 years	Total
Commitments under purchase agreements for property, plant and equipment	152.5	1.9	—	154.4
Contractual obligation to acquire intangible assets	249.4	954.9	516.8	1,721.1
Total	401.9	956.8	516.8	1,875.5

Other financial obligations were recognized at nominal value.

19 Other Non-Financial Liabilities

<i>(in millions €)</i>	December 31, 2023	December 31, 2022
Liabilities to employees	73.3	50.6
Liabilities from share-based payment arrangements	29.0	36.2
Liabilities from wage taxes and social securities expenses	15.1	761.8
Other	20.8	29.2
Total	138.2	877.8
Total current	125.1	860.8
Total non-current	13.1	17.0

20 Leases

20.1 Amounts Recognized in the Consolidated Statements of Financial Position

Right-of-Use Assets

The following amounts are presented as right-of-use assets within the consolidated statements of financial position as of the dates indicated:

<i>(in millions €)</i>	December 31, 2023	December 31, 2022
Buildings	209.8	206.5
Production facilities	—	3.0
Other operating equipment	4.6	2.4
Total	214.4	211.9

Additions to the right-of-use assets during the year ended December 31, 2023, were €66.4 million (during the year ended December 31, 2022: €118.3 million).

Lease Liability

The following amounts are included in lease liabilities, loans and borrowings as of the dates indicated:

<i>(in millions €)</i>	December 31, 2023	December 31, 2022
Current	28.1	36.0
Non-current	188.6	174.1
Total	216.7	210.1

20.2 Amounts Recognized in the Consolidated Statements of Profit or Loss

Depreciation Charge of Right-of-Use Assets

<i>(in millions €)</i>	Years ended December 31,		
	2023	2022	2021
Buildings	40.7	35.2	14.7
Production facilities	3.0	23.1	14.0
Other operating equipment	1.5	0.5	0.3
Total depreciation charge	45.2	58.8	29.0
Interest on lease liabilities	5.7	5.1	2.9
Expense related to short-term leases and leases of low-value assets	58.9	27.1	9.5
Total amounts recognized in profit or loss	109.8	91.0	41.4

20.3 Amounts Recognized in the Consolidated Statements of Cash Flows

During the year ended December 31, 2023, the total cash outflow for leases amounted to €46.0 million (during the year ended December 31, 2022: €46.2 million; during the year ended December 31, 2021: €17.0 million).

20.4 Extension Options

The Group has several lease contracts that include extension options. These options are negotiated by management to provide flexibility in managing the leased asset portfolio and align with the Group's business needs. Management exercises judgment in determining whether these extension options are reasonably certain to be exercised. The undiscounted potential

future lease payments, which relate to periods after the exercise date of renewal options and are not included in lease liabilities, amount to up to €157.2 million as of December 31, 2023, considering terms up until 2049 (as of December 31, 2022: €163.1 million considering terms up until 2049).

21 Related Party Disclosures

21.1 Parent and Ultimate Controlling Party

ATHOS KG, Holzkirchen, Germany is the sole shareholder of AT Impf GmbH, Munich, Germany and beneficial owner of our ordinary shares. ATHOS KG via AT Impf GmbH has de facto control over BioNTech based on its substantial shareholding, which practically enables it to exercise the majority of voting rights to pass resolutions at our Annual General Meeting, or AGM.

21.2 Transactions with Key Management Personnel

In May 2023, at the Annual General Meeting, our shareholders reappointed Ulrich Wandschneider and Michael Motschmann as members of the Supervisory Board. In addition, Nicola Blackwood was appointed to our Supervisory Board. She succeeded Christoph Huber, who left the Supervisory Board after reaching the applicable retirement age limit.

Key Management Personnel Compensation

Our key management personnel has been defined as the members of the Management Board and the Supervisory Board. Key management personnel compensation is comprised of the following:

<i>(in millions €)</i>	Years ended December 31,		
	2023	2022	2021
Management Board	8.3	15.0	20.4
Fixed compensation	3.9	2.9	2.2
Short-term incentive – first installment	0.7	0.6	0.6
Short-term incentive – second installment ⁽¹⁾	1.0	0.7	1.2
Other variable compensation ⁽²⁾	0.8	0.1	—
Share-based payments (incl. long-term incentive) ⁽³⁾	1.9	10.7	16.4
Supervisory Board	0.6	0.5	0.4
Total compensation paid to key management personnel	8.9	15.5	20.8

⁽¹⁾ The fair value of the second installment of the short-term incentive compensation which has been classified as a cash-settled share-based payment arrangement was determined pursuant to the regulations of IFRS 2 “Share-based Payments.” This table shows the pro-rata share of personnel expenses for the respective financial year that are recognized over the award’s vesting period beginning as of the service commencement date (date when entering or renewing service agreements) until each separate determination date and are remeasured until settlement date.

⁽²⁾ Includes a one-time signing and retention cash payment agreed when renewing the service agreement agreed with Sean Marett.

⁽³⁾ The fair value of the share-based payments was determined pursuant to the regulations of IFRS 2 “Stock-based Payments.” This table shows the pro-rata share of personnel expenses resulting from stock-based compensation for the respective financial year. During the years ended December 31, 2023, 2022, and 2021, the amounts included expenses derived from a one-time signing bonus granted to Jens Holstein as of his appointment to the Management Board in the form of 4,246 phantom shares.

Management Board members participated in our ESOP program (see Note 16) Out of the 5,152,410 option rights granted to our Management Board under the ESOP 2018 program 4,921,630 options were exercised during the year ended December 31, 2022. The remaining 230,780 option rights were exercised by Sean Marett in May 2023. As of December 31, 2023, no further options issued to our Management Board members are outstanding.

21.3 Related Party Transactions

The total amount of transactions with ATHOS KG or entities controlled by it was as follows for the periods indicated:

<i>(in millions €)</i>	Years ended December 31,		
	2023	2022	2021
Purchases of various goods and services from entities controlled by ATHOS KG	0.3	0.3	0.9
Purchases of property and other assets from entities controlled by ATHOS KG	—	62.5	—
Total	0.3	62.8	0.9

On December 22, 2022, we entered into a purchase agreement with Santo Service GmbH, pursuant to which we acquired the real estate property An der Goldgrube 12 and the existing laboratory and office building including any movable assets for a total consideration of €62.5 million. The purchase price was paid during the year ended December 31, 2022. Santo Service GmbH is wholly owned by AT Impf GmbH, that is controlled by ATHOS KG.

The outstanding balances of transactions with ATHOS KG or entities controlled by them were as follows as of the periods indicated:

<i>(in millions €)</i>	December 31, 2023	December 31, 2022
ATHOS KG	0.4	—
Total	0.4	—

None of the balances are secured and no bad debt expense has been recognized in respect of amounts owed by related parties.

22 Events After the Reporting Period

On February 8, 2024, we and Autolus Therapeutics plc, or Autolus, a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, announced a strategic collaboration aimed at advancing both companies' autologous CAR-T programs towards commercialization. We have entered into a license and option agreement and a securities purchase agreement under which we purchased \$200.0 million of Autolus' American Deposit Shares in a private placement closed on February 13, 2024 resulting in a stake in Autolus ordinary shares of 12.5%. Under the terms of the license and option agreement, we made a \$50.0 million upfront payment in exchange for the right to receive royalties on net sales of Autolus' lead asset obe-cel, co-commercialization options for Autolus' AUTO1/22 and AUTO6NG programs as well as an exclusive license and exclusive options to certain technologies owned by Autolus.

The Supervisory Board has appointed Annemarie Hanekamp to the Management Board as Chief Commercial Officer (CCO), effective as of July 1, 2024. She will take over the role from Sean Marett, who will retire as planned from the Management Board as of June 30, 2024.

DESCRIPTION OF SECURITIES

The following description sets forth certain material terms and provisions of ordinary shares and American Depositary Shares representing ordinary shares of BioNTech SE (“BioNTech,” the “Company,” “we,” “us,” and “our”) that are registered under Section 12 of the U.S. Securities Exchange Act of 1934, as amended. This description also summarizes certain provisions of our articles of association and German law as of the date of the filing of the Annual Report on Form 20-F of which this exhibit forms a part. This summary does not purport to be complete and is qualified in its entirety by the provisions of our articles of association filed with the Securities and Exchange Commission as an exhibit to the Annual Report on Form 20-F of which this exhibit forms a part, as well as to the applicable provisions of German legislation on stock corporations. We encourage you to read our articles of association and the applicable provisions of German law for additional information.

Ordinary Shares

We were incorporated as a German stock corporation (*Aktiengesellschaft*) with the legal name Petersberg 91. V AG under the laws of the Federal Republic of Germany on June 2, 2008. We changed our name to BioNTech AG on December 11, 2008. Effective as of March 8, 2019, the date on which the change of legal form and company was registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) of Mainz, Germany, we converted to a *Societas Europaea* with the legal name BioNTech SE. We completed our initial public offering in October 2019. The principal legislation under which we operate and our shares are issued are the Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE), the German Law on the Implementation of Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE) (*Gesetz zur Ausführung der Verordnung (EG) NR. 2157/2001 des Rates vom 8. Oktober 2001 über das Statut der Europäischen Gesellschaft (SE) (SE-Ausführungsgesetz—SEAG)*) and the German Stock Corporation Act (*Aktiengesetz*), in each case as amended.

We are registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) in Mainz, Germany, under number HRB 48720. Our statutory seat is in Mainz, Germany, and our registered office is An der Goldgrube 12, 55131 Mainz, Germany. Copies of our Articles of Association (*Satzung*) will be publicly available from the commercial register (*Handelsregister*) at the local court of Mainz, Germany, electronically at https://www.handelsregister.de/rp_web/welcome.xhtml and as an exhibit to this Annual Report.

Share Capital

We have share capital registered in the commercial register (*Handelsregister*) in the amount of €248,552,200, which is divided into 248,552,200 registered shares (*Namensaktien*). All shares are shares with no par value (*Stückaktien ohne Nennbetrag*) with a notional amount attributable to each ordinary share of €1. Each issued ordinary share is fully paid.

Form, Certification and Transferability of Shares

The form and contents of our share certificates, collective share certificates and global share certificates are determined by our Management Board. A shareholder’s right to certification of its shares is excluded, to the extent permitted by law and to the extent that certification is not required by the stock exchange on which the shares or rights or certificates representing them are admitted to trading. We are permitted to issue collective share certificates and global share certificates that represent multiple or all of our shares.

Our shares are freely transferable under German law.

Anti-takeover Provisions of Our Charter Documents

Our Articles of Association (*Satzung*) do not include any provisions that would have a direct effect of delaying, deferring or preventing a change of control. However, in the event of a hostile takeover, we could use our authorized capital to increase our share capital to issue new shares to an investor at a premium. An increase in the number of shares outstanding could have a negative effect on a party’s ability to carry out a hostile takeover. The provisions of German law relating to public bids and takeovers that require any such bids to be carried out in a manner designed to safeguard equal and fair treatment to all shareholders and give them a right to be bought out at an adequate compensation where a party acquires “control” (as such term is defined in such provisions) over the relevant company do not apply.

Future Changes to the Share Capital

Authorized Capital

Under the relevant law, the general meeting of a European stock corporation (*Societas Europaea*) governed by German law can authorize the Management Board to, with the consent of the Supervisory Board, issue shares in a specified aggregate nominal amount of up to 50% of the issued share capital of such company at the time the resolution becomes effective. The shareholders' authorization becomes effective upon registration in the commercial register (*Handelsregister*) and may extend for a period of no more than five years thereafter. Under § 4(5) of our Articles of Association (*Satzung*), the Management Board is authorized to increase our share capital, on one or more occasions, by a total of up to €122,657,313 by issuing, on one or more occasions, up to 122,657,313 new, registered shares with no par value (*Genehmigtes Kapital*), in each case with consent of the Supervisory Board. This authorization expires on June 21, 2026.

Any new shares issued from the authorized capital will participate in the profits starting with the fiscal year for which the annual financial statements have not yet been submitted to the general meeting at the time of registration of the implementation of the capital increase. Further details of a capital increase from the authorized capital may be specified by the Management Board.

Conditional Capital

Pursuant to § 4(6) of our Articles of Association (*Satzung*), our share capital is conditionally increased by €16,212,917 through issuance of new, registered shares with no par value (*Bedingtes Kapital ESOP 2017/2019*). The conditional capital may only be used to issue shares to the holders of option rights granted under our ESOP to members of our Management Board and to certain of our employees.

The conditional capital increase will only be implemented to the extent that stock options under our ESOP are exercised and said stock options are not serviced by our providing treasury shares or through cash payments. Any new shares issued under the conditional capital pursuant to the said § 4(6) of our Articles of Association (*Satzung*) shall be entitled to dividends from the beginning of the previous financial year in case they are created by the exercise of subscription rights until the start of the annual general meeting of the Company and otherwise from the beginning of the financial year in which they are created as a result of the exercise of the stock options.

Pursuant to § 4(7) of our Articles of Association (*Satzung*), our share capital is conditionally increased by €85,754,868 through issuance of new, registered shares with no par value (*Bedingtes Kapital WSV 2019*). The conditional capital may only be used to issue shares to the holders or creditors of option rights or conversion rights or those under an obligation to convert under warrant-linked or convertible bonds avail of their option rights or conversion rights or where they are under an obligation to convert, to the extent they satisfy their obligation to convert, or to the extent that we exercise a right to choose to grant our shares, in whole or in part instead of paying a monetary amount due, and to the extent cash compensation is not granted in each relevant case or treasury shares or shares of another stock-listed company are not utilized for servicing.

Any new shares issued under the said conditional capital pursuant to the said § 4(7) of our Articles of Association shall carry an entitlement to dividends from the beginning of the financial year in which they are created; however, as far as the law permits, the Management Board can confer dividend rights for new shares in derogation of the foregoing.

Pursuant to § 4(8) of our Articles of Association (*Satzung*), our share capital is conditionally increased by €8,418,091 through issuance of new, registered shares with no par value (*Bedingtes Kapital ESOP 2021*). The conditional capital serves exclusively to grant rights to the holders of stock options issued by the Company in accordance with the authorization granted by the Annual General Meeting on June 22, 2021 under agenda item 6 letter d) (the "Authorization 2021").

The conditional capital increase will only be implemented to the extent that stock options under our ESOP are exercised by the holders of the stock options issued by the Company on the basis of Authorization 2021 and such stock options are not settled by the Company with treasury shares or through cash payments. Any new shares issued under the conditional capital pursuant to § 4(8) of our Articles of Association (*Satzung*) shall participate in profits from the beginning of the preceding financial year in case they are created by the exercise of subscription rights until the start of the annual general meeting of the Company and otherwise from the beginning of the financial year in which they are created as a result of the exercise of the stock options.

Preemptive Rights

German law generally provides shareholders with preemptive rights when new shares convertible bonds, bonds with warrants, profit participation rights or participating bonds are issued. This requirement, however, may also be satisfied by way of a credit institution subscribing for the securities and then offering them to the shareholders for purchase (*mittelbares Bezugsrecht*).

Further, it is possible for a shareholder resolution approved by three-quarters of the share capital voting on the resolution to exclude preemptive rights both where the general meeting itself resolves that the new securities to be issued and in relation to the authorized capital, *i.e.*, an authorization to the Management Board to, with the consent of the Supervisory Board, resolve on the issuance of new securities; provided, however, that in each case the exclusion or the authorization to so exclude preemptive rights, respectively, must be justified by specific facts, in accordance with established case law of the German Federal Court of Justice (*BGH*). The German Federal Court of Justice (*BGH*) considers the exclusion of subscription rights justified if it (i) serves a purpose in the company's interests, (ii) is suitable for attaining such purpose, and (iii) is necessary and appropriate. Additionally, the management board must submit a written report to the shareholders' meeting in which it presents the reasons for the exclusion of the subscription rights.

Accordingly, under our Articles of Association (*Satzung*), the Management Board may, with the consent of the Supervisory Board, exclude such preemptive rights in a capital increase from the authorized capital in the following circumstances:

- to exclude fractional amounts from the subscription right;
- in the case of a capital increase against cash contributions, if the issue price of the new shares is not significantly lower than the market price of the company's shares already listed on the stock exchange at the time the issue price is finally determined. However, this authorization shall only apply subject to the provision that the shares issued excluding subscription rights in accordance with Section 186(3) Sentence 4 AktG may not exceed a total of 10% of the share capital either at the time this authorization takes effect or, if this amount is lower, at the time this authorization is exercised. This limit of 10% of the share capital includes shares which are issued or disposed of during the term of this authorization until the date of its exercise in direct or equivalent application of Section 186(3) Sentence 4 AktG. Shares which are used to service bonds with convertible or option rights or convertible obligations are to be offset against the 10% limit if these bonds were issued under exclusion of shareholder subscription rights in accordance with Section 186(3) Sentence 4 AktG during the entitlement period. Treasury shares are to be offset against the 10% limit, where they were disposed of by the company during the term of this authorization with the exclusion of subscription rights pursuant to or in analogous application of Section 186(3) Sentence 4 AktG;
- in the case of capital increases in exchange for contributions in kind, in particular in order to be able to offer the shares to third parties when purchasing companies, parts of companies or interests in companies as well as licenses or intellectual property rights;
- in order to grant subscription rights to new shares to holders of conversion or option rights in respect of bonds issued by the company or its subordinated domestic or foreign Group companies, to the extent to which they would be entitled after exercising their conversion or option rights or after fulfilling an agreed conversion obligation;
- to implement an election dividend by which shareholders are given the option to contribute their dividend entitlements (either in whole or part) as a contribution in kind against issuance of our new shares;
- in case shares are to be issued to a member of our Management Board or to another person who is employed by us or one of our affiliates, additional restrictions with regard to the shares issued may be agreed upon; and
- in order to be able to satisfy an option to acquire additional ordinary shares or American Depositary Shares that has been agreed with the issuing banks in connection with a public offering of our shares in the form of American Depositary Shares.

The total number of new shares issued from the authorized capital and under exclusion of subscription rights pursuant to bullets one through three and six above may not exceed 20% of the share capital, either at the time that the amendment to the Articles of Association (*Satzung*), resolved upon by the general meeting of June 26, 2020, has come into effect or, if lower, at the time of utilization of the authorization. To be counted against the aforementioned 20% limit are: (i) those shares issued or to be issued to service conversion or option rights or conversion or option obligations or tender rights of the issuer under bonds, if the bonds have been issued during the term of this authorization up to the time of its exercise, excluding the subscription rights of shareholders, as well as, to a certain extent (ii) treasury shares that have been disposed under exclusion of subscription rights during the term of this

authorization (except in the case of certain exceptions of the resolution to item no. 8 of the general meeting of August 19, 2019).

Shareholders' Meetings and Voting Rights

Pursuant to our Articles of Association (*Satzung*), shareholders' meetings may be held at our seat or in any municipality in Germany with more than 500,000 inhabitants. Generally, shareholders' meetings are convened by our Management Board, or our Supervisory Board. Shareholders representing in the aggregate at least five percent of our ordinary shares may, subject to certain formal prerequisites, request that a shareholders' meeting be convened. Shareholders representing in the aggregate at least five percent of our ordinary shares or owning shares with an aggregate nominal value of at least €500,000 may request the addition of one or several items to the agenda of any shareholders' meeting. Shareholders' meetings may be summoned either via publication in the German Federal Gazette (*Bundesanzeiger*) or via mail or via email, in each case generally at least 30 days before the meeting.

Shareholders may participate in and vote in the shareholders' meeting if they are registered as a shareholder with the Company's share register. A shareholder who wishes to attend the shareholders' meeting—either in person or by proxy, which may also be appointed by us (*Stimmrechtsvertreter*)—must register for the meeting, which registration must occur no later than six days before the meeting (or at a later date, if so determined by our Management Board).

Each share carries one vote at a shareholders' meeting. Resolutions are, in accordance with our Articles of Association (*Satzung*), generally taken by simple majority of the votes cast. However, under applicable German and European law, a number of resolutions must be passed by either a three-quarter majority of the votes cast or a three-quarter majority of the share capital represented at the meeting. The fact that in these cases the quorum is determined in relation to the share capital or shares present (as opposed to, for example, all shares eligible to vote) means that holders of a minority of our shares could potentially control the outcome of resolutions.

Claims against Directors and Shareholders' Derivative Actions

Under German law, generally, the company, rather than its shareholders, is the proper claimant in an action with respect to a wrong committed against the company, or in cases where there is an irregularity in the company's internal management or supervision. Therefore, such claims may only be raised by the company represented by its management board, or, in the case of a wrong committed by a member of the Management Board, by the Supervisory Board. This concerns, in particular, claims against members of the Management Board or the Supervisory Board.

However, pursuant to German case law, the Supervisory Board is obliged to pursue the company's claims against the Management Board, unless the interest of the company keeps them from doing so. Further, the Management Board, or, if a claim is against a member of the Management Board, the Supervisory Board, is obliged to pursue the company's claims against the designated individuals if so resolved by a simple majority of votes cast during a shareholders' meeting. With a simple majority of votes, shareholders can also request that a representative pursue the claim on behalf of the company. The court may appoint such a representative upon the request of shareholders holding at least 10% of the company's share capital or a participation of at least €1,000,000 in the share capital.

If the company is unable to fulfill its third-party obligations, the company's creditors may pursue the company's damage claims against members of the Management Board for certain wrongdoings.

Under certain circumstances, shareholders can bring forward damage claims of the company against its management on their own behalf. In order to bring forward such a claim one shareholder alone or together with other shareholders needs to hold at least 1% of the company's share capital or a participation of €100,000 in the share capital. Additionally, the claimant(s) must comply with special claim approval procedures conducted before a competent court which will allow the pertinent request only if there are circumstances justifying the assumption that damage has been afflicted on the company by improper conduct or a gross breach of the law or the articles of association.

Dividend Rights

Under German law, distributions of dividends on shares for a given fiscal year are generally determined by a process in which the Management Board and Supervisory Board submit a proposal to the company's annual general

shareholders' meeting held in the subsequent fiscal year and such annual general shareholders' meeting adopts a resolution.

German law provides that a resolution concerning dividends and distribution thereof may be adopted only if the company's unconsolidated financial statements prepared in accordance with German law show net retained profits. In determining the profit available for distribution, the result for the relevant year must be adjusted for profits and losses brought forward from the previous year and for withdrawals from or transfers to reserves. Certain reserves are required by law and must be deducted when calculating the profit available for distribution.

Shareholders generally participate in profit distributions in proportion to the number of shares they hold. Dividends on shares resolved by the general shareholders' meeting are paid annually, shortly after the general shareholders' meeting, in compliance with the rules of the respective clearing system. Dividend payment claims are subject to a three-year statute of limitation in the company's favor.

Authorization to Purchase and Sell Our Own Shares

We may not purchase our own shares unless authorized by the shareholders' meeting or in other very limited circumstances as set out in the German Stock Corporation Act. The Company's shareholders' meeting held on August 19, 2019 authorized the Management Board until August 18, 2024, provided it complies with the legal requirement of equal treatment, to acquire treasury shares up to a total of 10% of the Company's share capital at the time of the relevant resolution or at the time the authorization is exercised. These shares held by the Company (including shares attributable to it pursuant to the AktG) must never exceed 10% of the share capital. The shares may be purchased (i) through the stock exchange, (ii) by means of a public offer directed to all shareholders of the Company, (iii) by means of a public invitation to the shareholders to make a sales offer or (iv) from the Bill & Melinda Gates Foundation under very limited circumstances as specified in the authorization. Such shares may not be purchased for trading purposes. The Management Board is authorized to use the shares only as specified in the authorization.

Squeeze-Out of Minority Shareholders

Under German law, the shareholders' meeting of a stock corporation may resolve, upon request of a shareholder that holds at least 95% of the share capital, that the shares held by any remaining minority shareholders be transferred to the majority shareholder against payment of "adequate cash compensation" (*Ausschluss von Minderheitsaktionären*). This amount must take into account the full value of the company at the time of the resolution, which is generally determined using the future earnings value method (*Ertragswertmethode*).

A squeeze-out in the context of a merger (*umwandlungsrechtlicher Squeeze-Out*) only requires a majority shareholder to hold at least 90% of the share capital.

Liquidation Rights

Apart from liquidation, e.g., as a result of insolvency proceedings, we may be liquidated with a vote of the holders of at least three-quarters of the share capital represented at the shareholders' meeting at which such a vote is taken. If we are liquidated, any assets remaining after all of our liabilities have been paid off would be distributed among our shareholders in proportion to their holdings in accordance with German statutory law. The German Stock Corporation Act provides certain protections for creditors which must be observed in the event of liquidation.

Differences in Corporate Law

The applicable provisions of the SE Regulation in conjunction with the German Stock Corporation Act as applied to a European stock corporation that has its legal seat in Germany differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the SE Regulation in conjunction with the German Stock Corporation Act applicable to us and the General Corporation Law of the State of Delaware relating to shareholders' rights and protections. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Delaware law and European and German law.

European Union/Federal Republic of Germany

Delaware

Board System

A European stock corporation may choose to have a two-tier board structure composed of the Management Board (*Vorstand*) and the Supervisory Board (*Aufsichtsrat*). We have chosen this structure.

The Management Board is responsible for running the company's affairs and representing the company in dealings with third parties.

The Supervisory Board of a European stock corporation under German law has a control and supervisory function. The Supervisory Board does not actively manage the company but certain Management Board actions require the approval of the Supervisory Board.

Under Delaware law, a corporation has a unitary board structure, and it is the responsibility of the board of directors to appoint and oversee the management of the corporation on behalf of and in the best interests of the stockholders of the corporation.

Management is responsible for running the corporation and overseeing its day-to-day operations.

Appointment and
Number of Directors

Under applicable European and German law, a European stock corporation governed by German law with a share capital of at least €3 million generally must have at least two members on its Management Board and the number of members shall be determined by or in the manner provided in the company's articles of association.

The Supervisory Board must consist of at least three but—depending on the share capital—no more than 21 Supervisory Board members, whereby the number of Supervisory Board members must be divisible by three if this is necessary for the fulfilment of co-determination requirements. The articles of association of the company must specify if the Supervisory Board has more than three members.

Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws.

European Union/Federal Republic of Germany

Delaware

Removal of
Directors

Supervisory Board members are either appointed by the shareholders' meeting or delegated by one or more individual shareholders if so provided for in the company's articles of association. If the Supervisory Board consists of fewer members than is required to meet the quorum for resolutions (either statutory or pursuant to the company's articles of association), a competent court may appoint additional members as needed to meet the quorum. The provisions of German law in relation to employees' co-determination do not apply to the Company.

Members of the Management Board of a European stock corporation are appointed by the Supervisory Board for a maximum period of six years with an opportunity to be reelected. The articles of association may provide for a shorter term, which in our case is up to five years. The members of the Management Board may be reelected, even repeatedly. The Supervisory Board may remove a member of the Management Board prior to the expiration of his or her term only for cause, such as gross breach of duties (*grobe Pflichtverletzung*), the inability to manage the business properly (*Unfähigkeit zur ordnungsgemäßen Pflichtausübung*) or a vote of no-confidence during the shareholders' meeting (*Vertrauensentzug*). The shareholders themselves are not entitled to appoint or dismiss the members of the Management Board.

Under Delaware law, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board of directors is classified, stockholders may effect such removal only for cause; or (ii) in the case of a corporation having cumulative voting, if less than the entire board of directors is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.

European Union/Federal Republic of Germany

Delaware

Under European law, a member of the Supervisory Board of a company may be elected for a term of up to six years. The articles of association may provide for a shorter term. Our Supervisory Board members are, if the general meeting does not resolve on a shorter term, elected for a period up to the end of the general meeting deciding on the discharge for the fourth financial year after the election. Reelection, including repeated reelection, is permissible. Members of the Supervisory Board may be removed with or without cause by way of a general meeting resolution, with the applicable majority requirement depending on the relevant company's articles of association.

Vacancies on the Board of Directors

Under the law, vacant positions on the Management Board are filled by the Supervisory Board in accordance with the general rules of appointment, which provide that vacancies are filled by the simple majority of votes of Supervisory Board members present or represented by proxy at the vote (with, under certain circumstances, the chairman having a casting vote), unless otherwise provided by the company's articles of association. In case of emergencies, a vacant position on the Management Board may be filled by an individual appointed by the court. Vacant positions on the Supervisory Board are filled in accordance with the general rules of appointment.

Annual General Meeting

A European stock corporation which is governed by German law must hold an annual shareholders' meeting within six months of the end of its fiscal year. The annual shareholders' meeting must be held at a location determined by the articles of association. If the articles of association do not provide for a specific location, the shareholders' meeting shall be held at the company's seat or, if applicable, at the venue (in Germany) where its shares are listed.

Under Delaware law, vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) or by a sole remaining director unless (i) otherwise provided in the certificate of incorporation or by-laws of the corporation or (ii) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case a majority of the other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

Under Delaware law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the bylaws.

European Union/Federal Republic of Germany

Delaware

General Meeting

Under the law, extraordinary shareholders' meetings, in addition to the annual shareholders' meetings, may be called by either the Management Board, or by the Supervisory Board. Shareholders holding at least 5% of the company's share capital are entitled to request that an extraordinary shareholders' meeting be convened. In the event that the meeting is not then so convened, a competent court may order that the meeting be convened or authorize the shareholders or their representative to convene the meeting themselves.

Under Delaware law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.

Notice of General Meetings

Under applicable European and German law, unless a longer period is otherwise provided for in the articles of association or applies because of registration requirements stipulated in the articles of association, the shareholders must be given at least 30 days' advance notice of the shareholders' meeting. Such notices must at least specify the name of the company, the statutory seat of the company, and the location, date and time of the shareholders' meeting. In addition, the invitation must contain the agenda items as well as the Management Board's and the Supervisory Board's voting proposal for each agenda item and, depending on the circumstances, certain further information.

Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.

If all shareholders entitled to attend the shareholders' meeting are present or represented and do not object to the meeting being held, the formalities of calling and holding of a shareholders' meeting do not apply.

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Delaware

Proxy	<p>A shareholder may designate another person to attend, speak and vote at a shareholders' meeting of the company on such shareholder's behalf by proxy.</p> <p>With respect to Management Board meetings, a Management Board member may transmit its (written or verbal) vote via another Management Board member.</p> <p>With respect to Supervisory Board meetings, a Supervisory Board member may participate in voting by issuing a written vote to another Supervisory Board member or any third party entitled to attend the Supervisory Board meeting.</p>	<p>Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.</p>
Preemptive Rights	<p>Under the law applicable to European stock corporations governed by German law, existing shareholders have a statutory subscription right for any additional issue of shares or any security convertible into shares pro rata to the nominal value of their respective holdings in the company, unless (i) shareholders representing three-quarters of the registered share capital present at the shareholders' meeting have resolved upon the whole or partial exclusion of the subscription right and (ii) there exists good and objective cause for such exclusion. No separate resolution on the exclusion of subscription rights is required if all shareholders waive their statutory subscription rights.</p>	<p>Under Delaware law, stockholders have no preemptive rights to subscribe to additional issues of stock or to any security convertible into such stock unless, and except to the extent that, such rights are expressly provided for in the certificate of incorporation.</p>

European Union/Federal Republic of Germany

Delaware

Authority to Allot	Under applicable European and German law, the Management Board may not allot shares, grant rights to subscribe for or to convert any security into shares unless a shareholder resolution to that effect has been passed at the company's shareholders' meeting granting the Management Board with such authority—subject to the approval of the Supervisory Board—in each case in accordance with the provisions of the German Stock Corporation Act.	Under Delaware law, if the corporation's certificate of incorporation so provides, the board of directors has the power to authorize the issuance of stock. It may authorize capital stock to be issued for consideration consisting of cash, any tangible or intangible property or any benefit to the corporation or any combination thereof. It may determine the amount of such consideration by approving a formula. In the absence of actual fraud in the transaction, the judgment of the directors as to the value of such consideration is conclusive.
Liability of Directors and Officers	Under German law, any provision, whether contained in the company's articles of association or any contract or otherwise, that purports to exempt a Management or Supervisory Board member from any liability that would otherwise attach to such board member in connection with any negligence, default, breach of duty or breach of trust in relation to the company is void. Under German law, members of both the Management Board and members of the Supervisory Board are liable to the company, and in certain cases to third parties or shareholders, for any damage caused to them due to a breach of such member's duty of care. Apart from insolvency or special circumstances, only the company has the right to claim damages from members of either board. The company may waive claims for damages against a negligent Management or Supervisory Board member only after the expiry of three years.	Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director to the corporation and its stockholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for: <ul style="list-style-type: none">• any breach of the director's duty of loyalty to the corporation or its stockholders;• acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;• intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or• any transaction from which the director derives an improper personal benefit.

European Union/Federal Republic of Germany

Delaware

Voting Rights

Under the relevant European and German law, each share, except for statutory non-voting preferred shares (*nicht stimmberechtigte Vorzugsaktien*), entitles its holder to vote at the shareholders' meeting with, in the case of no-par value shares, each share conferring one vote. While German law does not provide for a minimum attendance quorum for shareholders' meetings, the company's articles of association may so provide. In general, resolutions adopted at a shareholders' meeting may be passed by a simple majority of votes cast, unless a higher majority is required by law or under the company's articles of association.

Delaware law provides that, unless otherwise provided in the certificate of incorporation, each stockholder is entitled to one vote for each share of capital stock held by such stockholder.

Shareholder Vote on
Certain Transactions

Under applicable European and German law, certain shareholders' resolutions of fundamental importance require the vote of at least three-quarters of the share capital present or represented in the voting at the time of adoption of the resolution. Resolutions of fundamental importance include, in particular, capital increases with exclusion of subscription rights, capital decreases, the creation of authorized or conditional share capital, the dissolution of a company, a merger into or with another company, split-offs and split-ups, the conclusion of inter-company agreements (*Unternehmensverträge*), in particular domination agreements (*Beherrschungsverträge*) and profit and loss transfer agreements (*Ergebnisabführungsverträge*).

Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires:

- the approval of the board of directors; and
- approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of a corporation entitled to vote on the matter.

European Union/Federal Republic of Germany

Standard of Conduct for Directors

Under applicable European and German law, both Management and Supervisory Board members must conduct their affairs with “the care and diligence of a prudent business man” and act in the best interest of the company. The scope of the fiduciary duties of Management and Supervisory Board members is generally determined by European and German legislation and by the courts.

Statutory and fiduciary duties of members of the Management Board to the company include, among others:

- to act in accordance with the law, the company’s articles of association and the rules of procedure for the Management Board, if any;
- to report to the Supervisory Board on a regular basis as well as on certain important occasions;
- to exercise reasonable care, skill and diligence;
- to maintain a proper accounting system;
- to not compete, directly or indirectly, with the company without permission by the supervisory board; and
- to secure that no further transactions are made in case of insolvency.

Statutory and fiduciary duties of members of the Supervisory Board to the company include, among others:

- to effectively supervise the Management Board’s handling of the company’s affairs;
- to evaluate and issue a resolution on certain transactions which can only be conducted by the Management Board after approval of the Supervisory Board;
- to approve the company’s financial statements;
- to appoint the Management Board members and to represent the company in transactions between the company and members of the Management Board; and
- to approve service contracts between individual members of the Supervisory Board and the company.

Delaware

Delaware law does not contain specific provisions setting forth the standard of conduct of a director. The scope of the fiduciary duties of directors is generally determined by the courts of the State of Delaware. In general, directors have a duty to act without self-interest, on a well-informed basis and in a manner they reasonably believe to be in the best interest of the stockholders.

Directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its stockholders. The duty of care generally requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. In general, but subject to certain exceptions, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation.

In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the stockholders.

European Union/Federal Republic of Germany

Stockholder Actions

Under German law, generally, the company, rather than its shareholders, is the proper claimant in an action with respect to a wrong committed against the company, or in cases where there is an irregularity in the company's internal management or supervision. Therefore, such claims may only be raised by the company represented by its Management Board, or, in the case of a wrong committed by a member of the Management Board, by the Supervisory Board.

Additionally, pursuant to German case law, the Supervisory Board is obliged to pursue the company's claims against the Management Board, unless the interest of the company keeps them from doing so.

The Management Board, or, if a claim is against a member of the Management Board, the Supervisory Board, is obliged to pursue the company's claims against the designated individuals if so resolved by a simple majority of votes cast during a shareholders' meeting. With a simple majority of votes, shareholders can request that a representative pursues the claim on behalf of the company.

If the company is unable to fulfill its third-party obligations, the company's creditors may pursue the company's damage claims against members of the Management Board for certain wrongdoings.

Under certain circumstances, shareholders can bring forward damage claims of the company against its management on their own behalf. In order to bring forward such a claim one shareholder alone or together with other shareholders needs to hold at least one percent of the company's share capital or a participation of €100,000 in the share capital. Additionally, the claimant(s) need(s) to pass through special claim approval procedures.

Delaware

Under Delaware law, a stockholder may initiate a derivative action to enforce a right of a corporation if the corporation fails to enforce the right itself. The complaint must:

- state that the plaintiff was a stockholder at the time of the transaction of which the plaintiff complains or that the plaintiff's shares thereafter devolved on the plaintiff by operation of law; and
- either (i) allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action, or (ii) or state the reasons for not making the effort.

Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.

American Depositary Shares

The Bank of New York Mellon, as depositary, will register and deliver the American Depositary Shares, or the ADSs. Each ADS will represent one share (or a right to receive one share) deposited with The Bank of New York Mellon SA/NV as custodian for the depositary in Germany. Each ADS will also represent any other securities, cash or other property which may be held by the depositary. The deposited shares together with any other securities, cash or other property held by the depositary are referred to as the deposited securities. The depositary's office at which the ADSs will be administered and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

You may hold ADSs either (i) directly (a) by having an American Depositary Receipt, or an ADR, which is a certificate evidencing a specific number of ADSs registered in your name, or (b) by having uncertificated ADSs registered in your name, or (ii) indirectly by holding a security entitlement in ADSs through your broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, or DTC. If you hold ADSs directly, you are a registered ADS holder, or an ADS holder. This description assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

As an ADS holder, we will not treat you as one of our shareholders and you will not have shareholder rights. European and German law governs shareholder rights. The depositary will be the holder of the shares underlying your ADSs. As a registered holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR. Those documents are filed as exhibits to the registration statement of which this prospectus forms a part.

Dividends and Other Distributions

How will ADS holders receive dividends and other distributions on the shares?

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, upon payment or deduction of its fees and expenses. You will receive these distributions in proportion to the number of shares your ADSs represent.

Cash. The depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some of the value of the distribution.*

Shares. The depositary may distribute additional ADSs representing any shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares. The depositary may sell a portion of the distributed shares (or ADSs representing those shares) sufficient to pay its fees and expenses in connection with that distribution.

Rights to purchase additional shares. If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in each

case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse. **In that case, you will receive no value for them.** The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of shares, new ADSs representing the new shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

Other Distributions. The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. **This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you.**

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

You may surrender your ADSs to the depositary for the purpose of withdrawal. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible. However, the depositary is not required to accept surrender of ADSs to the extent it would require delivery of a fraction of a deposited share or other security. The depositary may charge you a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

You may surrender your ADR to the depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

Voting Rights

How do ADS holders vote?

ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of the State of New York and the provisions of our articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.

Except by instructing the depositary as described above, you won't be able to exercise voting rights unless you surrender your ADSs and withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares. In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed or as described in the following sentence. If (i) we asked the depositary to solicit your instructions at least 30 days before the meeting date, (ii) the depositary does not receive voting instructions from you by the specified date and (iii) we confirm to the depositary that:

- we wish the depositary to vote uninstructed shares;
- we reasonably do not know of any substantial shareholder opposition to a particular question; and
- the particular question is not materially adverse to the interests of shareholders,

the depositary will consider you to have authorized and directed it to vote the number of deposited securities represented by your ADSs in favor of any resolution that we proposed in the invitation to the shareholders' meeting.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. **This means that you may not be able to exercise voting rights and there may be nothing you can do if your shares are not voted as you requested.**

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

Fees and Expenses

Persons depositing or withdrawing shares or ADS holders must pay:

For:

\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)

Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property

Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates

\$.05 (or less) per ADS

Any cash distribution to ADS holders

A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs

Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders

\$.05 (or less) per ADS per calendar year

Depositary services

Registration or transfer fees

Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares

Expenses of the depositary

Cable and facsimile transmissions (when expressly provided in the deposit agreement)

Converting foreign currency to U.S. dollars

Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes

As necessary

Any charges incurred by the depositary or its agents for servicing the deposited securities

As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

Payment of Taxes

You will be responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register any transfer of your ADSs or allow you to withdraw the deposited securities represented by your ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do by an ADS holder surrendering ADSs and subject to any conditions or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides it would not be lawful and practical to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender of those ADSs or cancel those ADSs upon notice to the ADS holders.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADRs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary

notifies ADS holders of the amendment. **At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.**

How may the deposit agreement be terminated?

The depositary will initiate termination of the deposit agreement if we instruct it to do so. The depositary may initiate termination of the deposit agreement if:

- 60 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment;
- we delist the ADSs from an exchange in the United States on which they were listed and do not list the ADSs on another exchange in the United States or make arrangements for trading of ADSs on the U.S. over-the-counter market;
- we delist our ordinary shares from an exchange outside the United States on which they were listed and do not list the shares on another exchange outside the United States;
- the depositary has reason to believe the ADSs have become, or will become, ineligible for registration on Form F-6 under the Securities Act;
- we appear to be insolvent or enter insolvency proceedings
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities or reverse previously accepted surrenders of that kind that have not settled if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, but, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith, and the depositary will not be a fiduciary or have any fiduciary duty to holders of ADSs;
- are not liable if we are or it is prevented or delayed by law or by events or circumstances beyond our or its ability to prevent or counteract with reasonable care or effort from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person;
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- the depositary has no duty to make any determination or provide any information as to our tax status, or any liability for any tax consequences that may be incurred by ADS holders as a result of owning or holding ADSs or be liable for the inability or failure of an ADS holder to obtain the benefit of a foreign tax credit, reduced rate of withholding or refund of amounts withheld in respect of tax or any other tax benefit.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

Your Right to Receive the Shares Underlying your ADSs

ADS holders have the right to cancel their ADSs and withdraw the underlying shares at any time except:

- when temporary delays arise because (i) the depository has closed its transfer books or we have closed our transfer books, (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting or (iii) we are paying a dividend on our shares;
- when you owe money to pay fees, taxes and similar charges; or
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, or DRS, and Profile Modification System, or Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is a feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of uncertificated ADSs, to direct the depository to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depository of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depository will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depository's reliance on and compliance with instructions received by the depository through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depository.

Shareholder Communications; Inspection of Register of Holders of ADSs

The depository will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depository will send you copies of those communications or otherwise make those communications available to you if we ask it to. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

Jury Trial Waiver

The deposit agreement provides that, to the extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depository arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws. If we or the depository opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law.

You will not, by agreeing to the terms of the deposit agreement, be deemed to have waived our or the depository's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

*** Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) the type of information that the Registrant treats as private or confidential.



DATE: 31 July 2023

DEED OF AMENDMENT OF A SHARE PURCHASE AGREEMENT DATED 10 JANUARY 2023

Between

THE FME SHAREHOLDERS' REPRESENTATIVE

THE INVESTOR SELLERS' REPRESENTATIVE

THE INSTITUTIONAL SELLERS

and

BIONTECH SE

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THIS DEED is made the 31st day of July 2023

BETWEEN:

- (1) [***] of [***] (the “**FME Shareholders’ Representative**”);
- (2) [***] of [***] (the “**Investor Sellers’ Representative**”);
- (3) [***];
- (4) [***];
- (5) [***];
- (6) [***];
- (7) [***];
- (8) [***];
- (9) [***],

(parties (3) – (9) together, the “**Institutional Sellers**”); and

- (10) **BIONTECH SE** (with its statutory seat in Mainz, registered in the commercial register of the local court of Mainz, Germany, under HBR 48720) whose registered office is at An der Goldgrube 12, 55131 Mainz, Germany (the “**Buyer**”),
(together, the “**Parties**”).

RECITALS:

- (A) On 10 January 2023, the Buyer, the Sellers (as defined in the Agreement) and InstaDeep Ltd (the “**Company**”) entered into a share purchase agreement (the “**Agreement**”) relating to the sale and purchase of certain of the shares in the issued share capital of the Company.
- (B) The Parties have agreed to amend the terms of the Agreement as provided in this deed.

IT IS AGREED as follows:

1. INTERPRETATION

- 1.1 Expressions defined in the Agreement shall (unless the context otherwise requires) have those meanings when used in this deed.
- 1.2 Headings are used in this deed for convenience only and shall not affect its interpretation.
- 1.3 The provisions of clause 1.2 (*Interpretation*) of the Agreement shall (unless the context otherwise requires) apply to this deed as if set out in full and as if all references to the Agreement were references to this deed.

2. AMENDMENT OF THE AGREEMENT

On and with effect from the date of this deed, the Agreement shall be amended so as to take the form set out in Schedule 1 to this deed (the “**Amended Agreement**”) and shall for all purposes be deemed as between the Parties to have been in such amended form when the Agreement was first constituted. For convenience only, Schedule 2 of this deed shows the changes (additions and deletions) implemented by virtue of this deed, in redline against the original form of the Agreement as signed on 10 January 2023.

3. SUPPLEMENT

- 3.1 Except as amended by this deed, the Agreement shall continue in full force and effect.
- 3.2 Notwithstanding any other provision of this deed, the provisions of this deed shall be without prejudice to any rights or claims of any Party arising under the terms of the Agreement prior to the date of this deed.

4. GENERAL

- 4.1 This deed, and any agreements and arrangements between the parties as set out in the Agreement which this deed expressly preserves, constitutes the whole and only agreement and understanding between the Parties in relation to the subject matter of the Agreement.
- 4.2 This deed may be executed in any number of counterparts and by the Parties on different counterparts. Each counterpart shall constitute an original of this deed but all the counterparts shall together constitute one and the same deed.
- 4.3 No term of this deed (whether express or implied) is enforceable pursuant to the Contracts (Rights of Third Parties) Act 1999 or otherwise by any person who is not a party to it (and, for avoidance of doubt, the terms of this deed may be enforced by each New FME Shareholder on becoming the registered holder of Ordinary Shares and/or Employee Shares and duly executing and delivering a Deed of Adherence).
- 4.4 The following terms of the Agreement shall apply to this deed as if those terms referred instead to this deed and were set out in full herein: clause 19.4 (*Variation*) and clause 27 (*Governing law and jurisdiction*).

IN WITNESS of which the Parties have executed this instrument as a deed and delivered it on the date first above written.

FME Shareholders' Representative

Executed as a deed by)
[***]) /s/ [***]
as the FME Shareholders' Representative for)
and on behalf of the FME Shareholders)
in the presence of:)

Name of witness: [***]
Signature: /s/ [***]
Address: [***]
[***]
Occupation: [***]

Investor Sellers' Representative

Executed as a deed by)
[***]) /s/ [***]
as the Investor Sellers' Representative for)
and on behalf of the Investor Sellers)
in the presence of:)

Name of witness: [***]
Signature: [***]
Address: [***]
[***]
Occupation: [***]

Institutional Sellers

[**]

[***]

Buyer

Signed as a deed by)

BIONTECH SE,)

a company incorporated in Germany, acting by)

Dr Sierk Poetting)

/s/ Sierk Poetting)

Authorised signatory)

Jens Holstein)

/s/ Jens Holstein)

Authorised signatory)

who, in accordance with the laws of that)
territory, is acting under the authority of the)
the company)

SCHEDULE 1

Amended Agreement

Agreement

relating to the sale and purchase of certain shares of the issued share capital of InstaDeep Ltd

Dated 10 January 2023

Documents in agreed form:

Signing Allocation Schedule

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This Agreement is made on 10 January 2023

Between:

- (1) **The persons** whose names and addresses are set out in Part 1 of Schedule 1, together with the New FME Shareholders as defined in clause 1.1 below, (the **"FME Shareholders"** and each, an **"FME Shareholder"**);
- (2) The persons whose names and addresses are set out in Part 2 of Schedule 1 and such other persons (who as of the date of this Agreement are FME Shareholders) as the Purchaser and the FME Shareholders' Representative may agree to classify as Investor Sellers before Completion (the **"Investor Sellers"** and each, an **"Investor Seller"**),
(together, the **"Sellers"** and each, a **"Seller"**);
- (3) **BioNTech SE** (with its statutory seat in Mainz, registered in the commercial register of the local court of Mainz, Germany, under HBR 48720) whose registered office is at An der Goldgrube 12, 55131 Mainz, Germany (the **"Purchaser"**); and
- (4) **InstaDeep Ltd** (with registration number 09816291) whose registered office is at 5 Merchant Square, London, England, W2 1AY (**"InstaDeep"**).

Background:

- (A) The Sellers are the legal and beneficial owners of the Completion Shares (save as set out in this Agreement).
- (B) The Sellers have agreed to sell, and the Purchaser has agreed to purchase the Completion Shares on the terms and subject to the Conditions set out in this Agreement.

This Deed witnesses as follows:

1. **Definitions and interpretation**

1.1 In this Agreement, including the Background, unless a contrary intention is expressly stated, the following definitions shall apply:

"2022 [*] SPA"** means the Share Purchase Agreement between (1) the Purchasers (as defined therein); (2) [***]; and (3) the Company, dated 6 December 2022.

"Accounts" means the Stand-alone Accounts and the Group Accounts.

"Accounts Date" means 31 December 2021.

"Act of God" means an unforeseeable grave natural phenomenon outside of human control/activity of an exceptional, inevitable, and irresistible nature, such as a flood, a drought, an earthquake, a windstorm or another natural catastrophe.

"Actual Adjustment Amount" means the aggregate of:

(a) the amount by which the Actual Cash is in excess or shortfall of the Target Cash Balance,

less

(b) the amount by which the Actual Debt is in excess of the Target Debt Balance (for the avoidance of doubt, no shortfall will occur),

plus / minus

(c) the amount of the difference between the Actual Working Capital and the Target Working Capital (which shall be a positive number if the Actual Working Capital is in excess of the Target Working Capital, or a negative number if the Actual Working Capital is less than the Target Working Capital).

"Actual Cash" means the aggregate Cash as at the Effective Time, as set out in the Completion Accounts.

"Actual Debt" means the aggregate Debt as at the Effective Time, as set out in the Completion Accounts.

"Actual Working Capital" means the aggregate Working Capital as at the Effective Time, as set out in the Completion Accounts.

"Agreement" means this agreement executed as a deed (including any schedule to it).

"Applicable Law" means (with respect to any person, property, transaction, event or other matter) any law, rule, statute, regulation, instrument, order, judgment, decree, treaty or other requirement having the force of law in any jurisdiction (collectively, the **"Law"**) relating or applicable to such person, property, transaction, event or other matter. **"Applicable Law"** also

includes, where appropriate, any interpretation of the Law (or any part thereof) by any person having jurisdiction over it or charged with its administration or interpretation.

"Applicable Jurisdiction" means any of the countries in which the Company has subsidiaries and branches from time to time being, at the date of this Agreement, Nigeria, Germany, the United States of America, Tunisia, France, the United Arab Emirates and South Africa.

"BioNTech Company Shares" means the [***] Ordinary Shares, (of which [***] held only beneficially as of the date of this Agreement pending stamping of a stock transfer form in respect of the [***] Shares and updating of the Company's register of members accordingly), [***] Class A Shares and [***] Class B Shares each of £0.00001 each in the capital of the Company held by the Purchaser immediately prior to Completion.

"Business" means the business carried on by the Group, or any part of it.

"Business Day" means a day (other than a Saturday, a Sunday or a public holiday) on which clearing banks are open for all normal banking business in the city of London, UK and Mainz, Germany, and **"Business Hours"** means the hours of 9am to 5pm on a Business Day.

"CA2006" means the Companies Act 2006.

"Cash" the aggregate amount of all unrestricted and freely available:

- (a) cash on hand;
- (b) cash standing to the credit of any account with a bank or other financial institution including all term deposits (for the avoidance of doubt, excluding any interest on such term deposits); and
- (c) cash equivalents;
- (d) any Transaction Expenses up to £[***] which are paid out and settled by and/or invoiced to the relevant Group Company on or prior to the Completion Date;
- (e) any cash owed to the Company by [***] in relation to the exercise of the options; and

less

- (f) any cash which is not freely available or convertible within [***] days after the Effective Time including deposits and loans which relate to the guarantee of contractual lease agreements,

in each case to which the Company or any of the Subsidiaries is beneficially entitled as at the Effective Time, calculated on a consolidated basis in accordance with the accounting principles, policies, standards, practices, evaluation rules and estimation techniques specified in Part 2 of Schedule 9 (*Completion Accounts*). An illustrative detailed mapping on account basis designated as "Cash" is set out in Part 3 of Schedule 9.

"CBT Condition" has the meaning set out in sub-clause 2.2(g).

"CJRS" means the coronavirus job retention scheme (as it has effect from time to time) that is the subject of the direction given by the Treasury on 15 April 2020 under section 76 of the Coronavirus Act 2020.

"Claim" means a Warranty Claim and/or a claim by the Purchaser against the Warrantors under the Tax Covenant (as the case may be).

"Class A Shares" means convertible preference A shares of £0.000001 each in the capital of the Company.

"Class B Shares" means convertible preference B shares of £0.000001 each in the capital of the Company.

"Client" means any person to whom or which the Group shall at any time during the [***] month period prior to Completion have provided Restricted Business.

"Company" means InstaDeep Ltd, details of which are set out in Part 1 of Schedule 2 (*The Company*).

"Company Intellectual Property" means the Intellectual Property owned, enjoyed, used or licensed by the Group or arising from the existence or activities of any Group Company.

"Completion" means the completion of the sale and purchase of the Completion Shares in accordance with this Agreement.

"Completion Accounts" means the completion accounts prepared and agreed or determined in accordance with Schedule 9 (*Completion Accounts*).

"Completion Allocation Schedule" means the schedule, substantially in the form of the Signing Allocation Schedule, setting out, amongst other matters, the details of the Sellers'

residential addresses and country of residence, the Sellers' holdings of the Completion Shares, the FME Retained French Shares and the FME 2024 French Shares and the allocation of the Consideration payable to each of them (including, in particular, the mix of cash and Consideration ADSs used to settle the Upfront Consideration), as prepared in accordance with sub-clause 4.5.

"Completion Date" means the date on which Completion occurs in accordance with the terms of this Agreement.

"Completion Disclosure Letter" means the letter from the Warrantors to the Purchaser delivered on Completion, disclosing matters arisen after the date of this Agreement that are exceptions to the Warranties to be given at the Completion Date, together with all documents annexed to it.

"Completion Fully-Diluted Shares" means, as at Completion, the total number of Shares that are in issue or are to be issued by the Company being:

- (a) the Completion Shares (including any Shares issued or to be issued pursuant to the New Awards);
- (b) the BioNTech Company Shares;
- (c) the FME Retained French Shares; and
- (d) the FME 2024 French Shares.

"Completion Shares" means the Investors Sellers' Shares and the FME Completion Shares.

"Conditions" means those matters set out in sub-clause 2.2 (*Conditions precedent*).

"Confirmatory IP Assignments" means the agreements in such form as may be agreed between the FME Shareholders' Representative and the Purchaser, to be entered into on or before Completion relating to the assignment of Intellectual Property identified by the Purchaser during its due diligence exercise in respect of the Transaction as not being sufficiently vested in the Company, between:

- (a) such persons identified by the Purchaser (acting reasonably) as being employed by, or otherwise having a contractual relationship or arrangement with, a Group Company as at the date of this Agreement pursuant to which they have created Intellectual Property in the execution of their duties and/or following the instructions of the relevant Group Company, and the relevant Group Company; and
- (b) the relevant Group Company identified in part (a) above and the Company,

and each a **"Confirmatory IP Assignment"**.

"Consideration" means the aggregate consideration payable by the Purchaser to the Sellers pursuant to sub-clauses 4.1 (*Consideration*) and 3.9 for the Consideration Shares, the FME Retained French Shares and the FME 2024 French Shares.

"Consideration ADSs" means American Depositary Shares issued pursuant to the Deposit Agreement representing the Consideration Shares.

"Consideration ADS Price" means [***].

"Consideration Increase" has the meaning set out in sub-clause 5.2(c) (*Purchase price adjustment*).

"Consideration Reduction" has the meaning set out in sub-clause 5.2(a) (*Purchase price adjustment*).

"Consideration Shares" means ordinary shares of the Purchaser that form a part of the Consideration.

"Contingent Consideration" means the Investor Sellers' Upfront Contingent Cash Consideration plus the Earn-out Consideration.

"Counsel" means a barrister of not less than 10 years' standing, having experience in claims similar to a relevant Outstanding Claim, as agreed by the Sellers' Representatives and the Purchaser, or failing such agreement, as appointed by the Chair for the time being of the Bar of England and Wales on the application of either party.

"Cybersecurity Requirements" means all laws, regulations, codes, mandatory guidance (from regulatory and advisory bodies), international and national standards, industry schemes and sanctions relating to security of network and information systems and security breach and incident reporting requirements which are from time to time applicable to the Company or any of the Subsidiaries (or any part of their business), including the Data Protection Laws.

"Dangerous Substance" means any natural or artificial substance, preparation (a mixture or solution of two or more substances) or biological agent (including, without limitation, radiation or sources of radiation) (whether in the form of a solid, liquid, gas or vapour), the presence, generation, transportation, storage, treatment, use or disposal of which (whether alone or in combination with any other substance) gives rise to a risk of causing harm to human health, comfort or safety or harm to any other living organism or causing damage to the environment, or any waste.

"Data Protection Laws" has the meaning set out in sub-clause 34 (*Compliance*) of Schedule 4 (*Non-Tax Warranties*).

"Data Room" means the "Project Interstellar" virtual data room hosted by HighQ and made available by the Sellers to the Purchaser from 5 December 2022 to and including 9 January 2023.

"Debt" in relation to the Company and the Subsidiaries, the aggregate amount of their respective borrowings and other financial indebtedness in the nature of borrowing, including:

- (a) borrowings from any bank, financial institution or other entity;
- (b) indebtedness arising under any bond, note, loan stock, debenture, commercial paper or similar instrument;
- (c) obligations under any conditional sale, title retention, forward sale or purchase or any similar agreement or arrangement creating obligations with respect to the deferred purchase price of property (other than customary trade credit given in the ordinary course of trading);
- (d) indebtedness under any hire purchase agreement or finance lease (whether for land, machinery, equipment or otherwise) which is a liability under applicable accounting standards;
- (e) any indebtedness for monies borrowed or raised under any other transaction that has the commercial effect of borrowing;
- (f) any preference shares or element of preference shares shown as liabilities as required by applicable accounting standards;
- (g) any liabilities to shareholders of the Company;
- (h) any provision, accruals or liabilities relating to financial instruments, excluding accrued interests on the financial deposits;
- (i) any provision, accruals, liabilities or receivables relating to income taxes (including corporation tax, corporate income tax or any similar tax on a company's income, profits or gains);
- (j) any provisions, accruals or liabilities relating to annual bonus to employees and the long-term bonus which refers to the period ending at the Effective Time including any social security contributions;
- (k) any provisions, accruals or liabilities relating to retirement obligations including, without limitation, in respect of France and Tunisia and including any social security contributions in respect thereof;
- (l) any provisions, accruals and liabilities relating to long term incentive plans and share-based payment in accordance with IFRS 2 if they are not settled as of the Effective Time;
- (m) any provisions, accruals and liabilities for taxes and levy resulting from the vesting or exercise of the options (share-based payments) and including the effects from the Options, and awards pursuant to the French Plan which are not vested or exercised as of the Effective Time;
- (n) any lease liability obligation according to IFRS 16;
- (o) any Transaction Expenses less the Transaction Expenses treated as Cash for the purposes of paragraph (d) of that definition;
- (p) the Paying Agent Fee;
- (q) the W&I Cost;
- (r) any minority interest which exists prior to and on the Completion Date (for the avoidance of doubt, the minority interest is the book value calculated by multiplying the minority share interest with the net assets as of the Completion Date); and

- (s) all unpaid accrued interest on any borrowings or indebtedness referred to in the paragraphs above, together with any prepayment premiums or other penalties, fees, expenses or breakage costs arising (or which would arise) in connection with the repayment of any such borrowings or indebtedness,

as at the Effective Time, calculated on a consolidated basis in accordance with the accounting principles, policies, standards, practices, evaluation rules and estimation techniques specified in Part 2 of Schedule 9 (*Completion Accounts*). An illustrative detailed mapping on account basis designated as "Debt" is set out in Part 3 of Schedule 9.

"Deed of Adherence" means the deed of adherence substantially in the agreed form under which a New FME Shareholder agrees to adhere to the terms of this Agreement as a Seller in respect of the Shares acquired, or to be acquired, by them from the New Awards.

"Deposit Agreement" means the Deposit Agreement dated 9 October 2019, as amended from time to time, between the Purchaser, The Bank of New York Mellon, as depository (the **"Depository"**) and all Owners and Holders (each as defined in the Deposit Agreement), from time to time, of American Depositary Shares issued thereunder.

"Determination Date" means the date of agreement or determination of the Completion Accounts in accordance with Schedule 9 (*Completion Accounts*).

"Disclosed" means fairly disclosed to the Purchaser for the purposes of this Agreement in the Disclosure Documents and **"fairly"** means disclosed with sufficient particularity to enable the Purchaser to assess the impact on the Group of the matter disclosed and to properly identify the nature and scope of the matter disclosed and **"Disclose"** shall be construed accordingly.

"Disclosure Documents" means:

- (a) the Signing Disclosure Letter and the Completion Disclosure Letter (in each case, including the general disclosures contained therein); and
- (b) the documents in the Data Room, including all documents and answers provided as part of the Q&A function.

"Disposal" means the transfer, sale, disposal of, or the creation of any Encumbrance over, or the entry into any agreement to do any of the same in relation to (in each case whether directly, indirectly, contingently or otherwise) any Consideration Shares or any Interest in Consideration Shares, and "Dispose" shall be construed accordingly.

"Dispute Notice" has the meaning set out in Schedule 9 (*Completion Accounts*).

"Due Amount" means the amount (if any) due for payment to the Purchaser by those Sellers due to receive the Earn-out Consideration in respect of and only to the extent of their pro-rata liability for a Resolved Claim.

"Earn-Out" means the proportion of the Consideration calculated on a contingent basis during the Earn-out Period in respect of the satisfaction of the Milestones set out in Schedule 10 (*Calculation of Earn-out Consideration*).

"Earn-Out Consideration" has the meaning set out in Schedule 10 (*Calculation of Earn-out Consideration*).

"Earn-Out Consideration Completion Date" means the date being the 20th Business Day following the end of the Earn-Out Period.

"Earn-Out Period" means the period commencing on the Completion Date and ending on the third anniversary of the Completion Date.

"Effective Time" means 11:59pm (GMT) on the date of Completion.

"EIP Conditions" means (i) the CBT EIP Condition (as defined in the Purchaser's Employee Incentive Plan) and (ii) the registration with the South African Reserve Bank;

"EMI Option" means a share option granted pursuant to the Stock Option Plan that is intended to qualify as an Enterprise Management Incentive option in accordance with section 527(4) and Schedule 5 of ITEPA.

"Employee Shares" means non-voting ordinary shares of £0.000001 each in the capital of the Company.

"Encumbrance" means any interest or equity of any person (including any right to acquire, option or right of pre-emption or conversion) or any mortgage, charge, pledge, lien, assignment, hypothecation, security interest, title retention, or any other security agreement or arrangement, or any agreement to create any of the above.

"Estimated Adjustment Amount" means the aggregate of:

- (a) the amount by which the Estimated Cash is in excess or shortfall of the Target Cash Balance,
less
- (b) the amount by which the Estimated Debt is in excess of the Target Debt Balance (for the avoidance of doubt, no shortfall will incur),
plus / minus
- (c) the amount of the difference between the Estimated Working Capital and the Target Working Capital (which shall be a positive number if the Estimated Working Capital is in excess of the Target Working Capital, or a negative number if the Estimated Working Capital is less than the Target Working Capital),

as provided pursuant to clause 6 (*Pre-Completion obligations*) and set out in the Estimates Notice.

"Estimated Cash" means the Sellers' reasonable good faith estimate of Cash of the Group as at the Effective Time, as provided pursuant to clause 6 (*Pre-Completion obligations*) and set out in the Estimates Notice.

"Estimated Debt" means the Sellers' reasonable good faith estimate of Debt of the Group as at the Effective Time, as provided pursuant to clause 6 (*Pre-Completion obligations*) and set out in the Estimates Notice.

"Estimated FME Shareholders' Upfront Consideration" means the £price per share calculated in accordance with the Completion Allocation Schedule after including therein:

- (a) the Estimated Cash, Estimated Debt and the Estimated Working Capital amounts set out in the Estimates Notice and reflecting (if applicable) any increase or reduction of the FME Shareholders' Upfront Consideration as a result of the Estimated Adjustment Amount;
- (b) the [***] as a deduction in respect of the Completion Fully Diluted Consideration Shares held or to be held by FME Shareholders; and
- (c) [***].

"Estimated Liability" means, in relation to an Outstanding Claim, a genuine and bona fide estimate of the amount of the liability to the Purchaser of any relevant Seller who is due to receive Earn-Out Consideration if the Outstanding Claim was to be resolved in the Purchaser's favour, as agreed or determined in accordance with sub-clause 19.12(b).

"Estimated Sellers' Upfront Payment" means the £price per share calculated in accordance with the Completion Allocation Schedule after inserting the Estimated Cash, Estimated Debt and the Estimated Working Capital amounts set out in the Estimates Notice and reflecting (if applicable) any increase or reduction of the Investor Sellers' Upfront Consideration as a result of the Estimated Adjustment Amount.

"Estimated Tax Withholding" means, in relation to an FME Shareholder who is exercising an Option on or immediately before Completion and in respect of whom an Option Tax Liability will arise, the estimated amount of that Option Tax Liability as set out in the Completion Allocation Schedule.

"Estimated Working Capital" means the Sellers' reasonable good faith estimate of Working Capital of the Group as at the Effective Time, as provided pursuant to clause 6 (*Pre-Completion obligations*) and set out in the Estimates Notice.

"Estimates Notice" has the meaning set out in sub-clause 6.3 (*Pre-Completion obligations*).

"Exchange Rate" means with respect to a particular currency for a particular day the spot rate of exchange (the closing mid-point) for that currency into sterling on such date as published by the European Central Bank or where no such rate is published in respect of that currency for such date at the rate quoted by Bloomberg FX Fixings (<https://www.bloomberg.com/markets/currencies/fix-fixings>) as at 4:00pm London time on such date.

"Exchange Shares" means the Shares held by a Seller as at the date of this Agreement, being:

- (a) in respect of any FME Shareholder, the Shares set out against that FME Shareholder's name in any of column C1, C2 or E2 of the table set out in Part 1 of Schedule 1; and
- (b) in respect of any Investor Seller, the Shares set out against that Investor Seller's name in any of columns C1 to C4 (inclusive) of the table set out in Part 2 of Schedule 1.

"Existing Options" means the options to subscribe for Ordinary Shares or Employee Shares granted pursuant to the Stock Option Plan on or before the date of this Agreement.

"FME 2024 French Shares" means the Ordinary Shares set against that FME Shareholder's name in column E5 of the table set out in Part 1 of Schedule 1 (being Ordinary Shares that remain subject to a French Award and which, following a proposed amendment to the French Plan to be made with effect from Completion, will vest on [***]) but excluding any such Ordinary Shares to the extent that the applicable French Award held by the FME Shareholder lapses before Completion in accordance with the terms of the French Plan.

"FME Cash in Hand" means [***]% of (i) the Estimated Sellers' Upfront Payment *multiplied by* (ii) the number of FME Completion Shares.

"FME Completion Shares" means all the Shares held by the FME Shareholders at Completion which, in respect of each FME Shareholder, will consist of:

- (a) the Ordinary Shares set against that FME Shareholder's name in column C1 of the table set out in Part 1 of Schedule 1, being Ordinary Shares held by that FME Shareholder as at the date of this Agreement (other than Ordinary Shares that remain subject to a French Holding Period);
- (b) the Employee Shares set against that FME Shareholder's name in column C2 of the table set out in Part 1 of Schedule 1, being Employee Shares held by that FME Shareholder as at the date of this Agreement;
- (c) the Ordinary Shares set against that FME Shareholder's name in column D1 of the table set out in Part 1 of Schedule 1 (being Ordinary Shares that the FME Shareholder will acquire from the exercise of Existing Options immediately before Completion) but excluding any such Ordinary Shares to the extent that the applicable Existing Option held by the FME Shareholder lapses before Completion in accordance with the terms of the Stock Option Plan;
- (d) the Employee Shares set against that FME Shareholder's name in column D2 of the table set out in Part 1 of Schedule 1 (being Employee Shares that the FME Shareholder will acquire from the exercise of Existing Options immediately before Completion) but excluding any such Employee Shares to the extent that the applicable Existing Option held by the FME Shareholder lapses before Completion in accordance with the terms of the Stock Option Plan;
- (e) the Ordinary Shares set against that FME Shareholder's name in column E1 of the table set out in Part 1 of Schedule 1 (being Ordinary Shares that will be issued to that the FME Shareholder immediately before Completion in connection with the vesting of French Awards) but excluding any such Ordinary Shares to the extent that the applicable French Awards held by the FME Shareholder lapse before Completion in accordance with the terms of the French Plan;
- (f) if Completion arises after the date set against that FME Shareholder's name in column E4 of the table set out in Part 1 of Schedule 1, the Ordinary Shares set against that FME Shareholder's name in column E2 of the table set out in Part 1 of Schedule 1 (being Ordinary Shares held by that FME Shareholder as at the date of this Agreement that remain subject to a French Holding Period but which cease to be subject to that French Holding Period on or before Completion);
- (g) if Completion arises after the date set against that FME Shareholder's name in column E4 of the table set out in Part 1 of Schedule 1, the Ordinary Shares set against that FME Shareholder's name in column E3 of the table set out in Part 1 of Schedule 1 (being Ordinary Shares that will be issued to that the FME Shareholder immediately before Completion in connection with vesting of French Awards) but excluding any such Ordinary Shares to the extent that the applicable French Award held by the FME Shareholder lapses before Completion in accordance with the terms of the French Plan; and
- (h) any Employee Shares and/or Ordinary Shares issued to an FME Shareholder on or before Completion pursuant to the terms of, and/or following the exercise of, a New Award.

"FME Holdback Amount" means [***]% of the FME Cash in Hand in respect of the FME Completion Shares.

"FME Retained French Shares" means:

- (a) if Completion arises on or before the date set against that FME Shareholder's name in column E4 of the table set out in Part 1 of Schedule 1, the Ordinary Shares set against that FME Shareholder's name in column E2 of the table set out in Part 1 of Schedule 1

(being Ordinary Shares held by that FME Shareholder that, as at Completion, remain subject to a French Holding Period); and

- (b) if Completion arises on or before the date set against that FME Shareholder's name in column E4 of the table set out in Part 1 of Schedule 1, the Ordinary Shares set against that FME Shareholder's name in column E3 of the table set out in Part 1 of Schedule 1 (being Ordinary Shares that remain subject to a French Award that has not vested as at Completion but which is due to vest in May or June 2023) but excluding any such Ordinary Shares to the extent that the applicable French Award held by the FME Shareholder lapses before Completion in accordance with the terms of the French Plan.

"FME Shareholders' Representative" means [***] or such other person as the majority by value of Consideration receivable by the FME Shareholders may notify to the Purchaser in writing from time to time.

"FME Shareholders' Transaction Tax Liability" means, in respect of an FME Shareholder, the sum of:

- (a) the amount of any Option Tax Liability, or any personal tax liability of such FME Shareholder, that arises as a result of any exercise of an Option immediately before Completion;
- (b) the amount of any personal tax liability of such FME Shareholder that arises as a result of, or in connection with, the sale of any Completion Shares in accordance with this Agreement (provided that such personal tax liability is payable in respect of the tax year in which Completion occurs); and
- (c) the amount of any personal tax liability of such FME Shareholder that arises as a result of, or in connection with, the sale of any FME Retained French Shares and/or FME 2024 French Shares in accordance with this Agreement (provided that such personal tax liability is payable in respect of the tax year in which the sale of those Shares to the Purchaser takes place),

and, for the purposes of estimating an FME Shareholders' Transaction Tax Liability under this Agreement, the parties agree that, except for anything which can be factored in as a result of running dummy payroll runs in advance of Completion to the extent feasible: (1) no account will be taken of any reliefs that are personal to an FME Shareholder and which would require knowledge of the FME Shareholder's personal circumstances; and (2) all taxes will be estimated using the highest marginal rate of tax, unless the relevant payments are processed through a Group Company payroll and such reliefs and / or tax rates are taken into account in respect of such payment.

"FME Shareholders' Upfront Cash Completion Payment" means:

- (a) the FME Cash in Hand *plus*
- (b) the FME Shareholders' Transaction Tax Liability of all FME Shareholders in respect of the FME Completion Shares.

"Founder Sellers" means [***] and [***] details for whom are set out in Part 1 of Schedule 1 (and each a " **Founder**").

"French Award" means a right to acquire Ordinary Shares granted by the Company under the French Plan before the date of this Agreement.

"French Holding Period" means a Holding Period (as such term is defined in the French Plan) applying to Ordinary Shares acquired pursuant to a French Award.

"French Plan" the allocation plan of performance shares adopted by the Company on 21 August 2019 in respect of the employees of InstaDeep SAS.

"Good Faith" means acting honestly, reasonably and with fair dealing, having regard to (i) the collective interests of the parties represented and (ii) the provisions, aims and purposes of this Agreement, the Paying Agent Agreements and, if applicable, the Institutional Sellers' Representative Agreement, but without an obligation to subordinate one's own interests to the interests of the others.

"Governmental Authority" means any governmental authority in the United Kingdom, France, United Arab Emirates, South Africa, Tunisia, Germany, United States of America, Nigeria or any other country in which a Group Company conducts, or has conducted in the previous 2 years preceding the date of this Agreement, its business and includes any district, county, federal, state, provincial, municipal or similar authorities.

"Group Accounts" means, in respect of the Company, the audited consolidated balance sheet as at that date and the audited consolidated income statement for that period (including all documents required by Applicable Law to be annexed to them for that period).

"Group Companies" or **"Group"** means the Company, any holding company and any subsidiary and any subsidiary undertaking of the Company or such companies (as set out in Part 2 of Schedule 2 (*The Group Companies*)) and **"Group Company"** means any one of them.

"[*]Shares"** means the Shares transferred pursuant to the terms of the 2022 [***]SPA.

"Holdback Amount" means the FME Holdback Amount and the Investors Holdback Amount.

"holding company" has the meaning set out in Section 1159, CA2006.

"HMRC" has the meaning set out in the Tax Schedule.

"ICAEW President" shall have the meaning given to it in sub-clause 19.11 (*Independent Expert*).

"IFRS" means International Financial Reporting Standards (including international accounting standards, international financial reporting standards and interpretations of such standards) adopted for use in the UK under the International Accounting Standards and European Public Limited-Liability Company (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019/685) and in force for the accounting period ending on the Accounts Date.

"Indemnified Losses" has the meaning set out in the Paying Agent Agreements and each an **"Indemnified Loss"**.

"Independent Expert" means an independent expert whose appointment and terms of reference are governed by sub-clause 19.11 (*Independent Expert*).

"Instadeep Tunisia" means InstaDeep SARL, details of which are set out in Part 2 of Schedule 2 (*The Group Companies (and branches)*).

"Institutional Sellers" means [***].

"Institutional Sellers' Representative" means [***] or such other person as the Institutional Sellers (acting jointly on a unanimous basis) may notify to the Purchaser in writing from time to time.

"Intellectual Property" means any intellectual property or similar proprietary right, including all patents and patent applications, inventions (whether or not patentable), trade marks, trade names whether or not registered or capable of registration, registered designs, design rights, domain names, copyrights, database rights, the right to apply for and applications for any of the preceding items, together with the rights in inventions, processes, software, know how, trade or business secrets, confidential information or any process or other similar right or asset capable of protection enjoyed, owned, used or licensed and all other intellectual and industrial property rights throughout the world arising directly or indirectly and all licences of the intellectual property referred to above.

"Interest" means any legal or beneficial interest or any other interest as defined in section 820 (when read with sections 821 to 825 inclusive) of the CA 2006 and **"Interested"** shall be construed accordingly.

"International Armed Conflict" means all cases of:

- (a) the state of war declared in accordance with the laws of England and Wales; or
- (b) any other armed conflict with significant participation of the British Armed Forces which may arise between two or more states, even if the state of war is not recognized by one of them; or
- (c) partial or total occupation of the territory of the UK, even if the said occupation meets with no armed resistance; or
- (d) any other armed conflicts in which people are fighting against colonial domination and alien occupation and against racist regimes in the exercise of their right of self-determination.

"Investors Holdback Amount" means [***]% of (i) the Estimated Sellers' Upfront Payment **multiplied by** (ii) the number of Completion Shares held by the Investor Sellers.

"Investor Sellers' Representative" means [***] or such other person as the majority by value of Consideration receivable by the Investor Sellers (excluding the Institutional Sellers) may notify to the Purchaser in writing from time to time.

"Investor Sellers' Shares" means the following fully paid and issued shares:

- (a) [***] Ordinary Shares;
- (b) [***] Class A Shares;
- (c) [***] Class B Shares; and
- (d) [***] Employee Shares,

held by the Investor Sellers in the proportions set out in Part 2 of Schedule 1 and any other shares in the capital of the Company that the Purchaser and the FME Shareholders' Representative may agree to classify as Investor Sellers' Shares before Completion.

"Investor Sellers' Upfront Contingent Cash Consideration " means the sum of £[***] per share held.

"ITEPA" has the meaning given to it in the Tax Schedule.

"IT Systems" has the meaning set out in sub-clause 30.1 (*Information technology*) of Schedule 4.

"Key Employees" means those persons listed in Part 2 of Schedule 10.

"Leases" means all leases (including underleases) under which the Properties are held, particulars of which are set out in Part 2 of Schedule 3 (*The Properties*) and **"Lease"** means any one of them.

"Lock-up Period" has the meaning set out in clause 18.1.

"[*]"** means [***] acting in its capacity as paying agent and escrow agent under the relevant Paying Agent Agreement, or such other paying agent and/or escrow agent as may be agreed between the Purchaser, the FME Shareholders Representative, the Investor Sellers' Representative and the Institutional Sellers.

"Management Accounts" means each of the unaudited consolidated monthly management accounts (including a balance sheet and an income statement) for the Group for the period from the Accounts Date to 31 October 2022.

"Material Adverse Change" means the occurrence or commencement, between the date of this Agreement and Completion, of a Material Adverse Change Event which is reasonably likely to sustain beyond Completion and which results in the Group as a whole having suffered any one or more impairments (as construed under IFRS as in force on the date of this Agreement, but ignoring for these purposes any impairments occurring as a result of any future changes in accounting standards or principles or interpretations of general application in relation thereto) of the assets of the Group and/or having incurred one or more one-off costs or liabilities outside the ordinary course of business which, taken together, have resulted in the total assets of the Group on a consolidated basis being reduced by more than [***], where:

"Material Adverse Change Event" means:

- (a) an Act of God in the UK;
- (b) an International Armed Conflict on the territory of the UK; or
- (c) a Non-International Armed Conflict on the territory of the UK;

"Milestones" has the meaning set out in Part 1 of Schedule 10.

"Minority Share Transfers" means:

- (a) in respect of InstaDeep Tunisia, the transfer of 1 share in the capital of InstaDeep Tunisia from [***] to the Company; and
- (b) in respect of InstaDeep Nigeria, the transfer of 10,000 shares in the capital of InstaDeep Nigeria from [***] to InstaDeep SAS,

and each a **"Minority Share Transfer"**.

"New Articles of Association" means the new articles of association to be adopted by the Company with effect from Completion.

"New Award" means an option or other right to acquire Employee Shares and/or Ordinary Shares granted after the date of this Agreement and before the Completion Date pursuant to either the French Plan or the Stock Option (or pursuant to any other arrangement with the prior written agreement of the Purchaser).

"New FME Shareholder" means any person not set out in Part 1 of Schedule 1:

- (a) to whom a New Award is granted after the date of this Agreement and before Completion;

- (b) who will be issued Ordinary Shares and/or Employee Shares on or before Completion in respect of that New Award; and
- (c) who, on or before Completion, has signed a Deed of Adherence.

"Non-International Armed Conflict" means all armed conflicts, other than International Armed Conflicts, which take place on the territory of the UK between the British Armed Forces and dissident armed forces or other organised armed groups which, under responsible command, exercise control over a part of its territory, such control enabling them to carry out sustained and concerted military operations, but in each case excluding situations of internal disturbances and tensions, such as riots, isolated and sporadic acts of violence and other acts of a similar nature.

"Non-Tax Claim" means any Claim which is not a Tax Claim.

"Non-Tax Warranties" means the warranties set out in Schedule 4 (*Non-Tax Warranties*).

"Non-US FME Shareholders" means the FME Shareholders, other than the US FME Shareholders.

"Non-US FME Shareholders' ADS Letter of Representation" means the letter of representation, in a form to be agreed between each Non-US FME Shareholder and the Purchaser acting reasonably, to be provided by each Non-US FME Shareholder at Completion to the Purchaser in respect of the Consideration Shares and Consideration ADSs.

"Notice" includes any notice, demand, consent or other communication.

"Open Source Materials" means any publicly available software or material that contains or is derived from, or is distributed or licensed:

- (a) as free, libre or open-source software;
- (b) under a licensing or distribution arrangement that requires, as a condition of use, modification and/or distribution of such software or material, that other software incorporated into, derived from or distributed with such software or material be:
 - (i) disclosed or distributed in source code form;
 - (ii) licensed for the purpose of making derivative works;
 - (iii) licensed to permit decompilation, disassembly or reverse engineering of licensee's products; or
 - (iv) redistributable at no charge; or
- (c) under a licensing or distribution arrangement similar to (a) or (b) including but not limited to the GNU General Public License, GNU Lesser General Public License and Mozilla Public License.

"Optionholders" means the FME Shareholders who, under the Stock Option Plan, hold an Option that is to be exercised on or immediately before Completion.

"Options" means the Existing Options and the New Awards.

"Option Exercise Documents" means:

- (a) in relation to the Options (excluding any New Award in the form of an RSU Award):
 - (i) a sale notice provided by the Company to each Optionholder inviting such Optionholder to exercise their Options;
 - (ii) a notice of exercise provided by each Optionholder (or a duly appointed attorney) under which each such Optionholder has elected and authorised their employing company to deduct sufficient amounts to settle the Option Exercise Price and Option Tax Liability arising on exercise of their Options;
 - (iii) where applicable, a duly executed joint election pursuant to section 431 of ITEPA for full disapplication of Chapter 2 ITEPA in relation to the exercise of the Options made by each Optionholder's employing entity that is a member of the Group and each Optionholder (or a duly appointed attorney);
 - (iv) a power of attorney to, inter alia, facilitate the exercise of the Options and the sale of the resulting shares provided by each Optionholder; and
 - (v) the board minutes of the Company approving the exercise of the Options and the issue and allotment of the Shares in respect of the exercise of the Options to the Optionholders; and
- (b) in relation to the RSU Awards:

- (i) where applicable, a duly executed joint election pursuant to section 431 of ITEPA for full disapplication of Chapter 2 ITEPA in relation to the Completion Shares to be issued to the RSU Holder, made by each RSU Holder's entity that is a member of the Group and the RSU Holder (or a duly appointed attorney);
- (ii) a power of attorney given by each RSU Holder to, inter alia, facilitate the sale of the Completion Shares held by the RSU Holder; and
- (iii) the board minutes of the Company approving the issue and allotment of the Shares in respect of the RSU Awards to the RSU Holders,

each in a form to be agreed between each RSU Holder and the Purchaser acting reasonably.

"Option Exercise Monies" means the aggregate exercise price payable by an Optionholder on the exercise of his/her Option.

"Option Tax Liability" means the amount of any income tax under PAYE and Class 1 employee National Insurance contributions (including secondary Class 1 (employer's) National Insurance contributions), or any other income tax, social security liability or other similar imposts or levies which become payable by a Group Company in any jurisdiction other than the UK, on exercise of an Option or, on the vesting in case of an RSU Award, by an FME Shareholder.

"Ordinary Shares" means ordinary shares of £0.000001 each in the capital of the Company.

"Outstanding Claim" means such portion of a claim under this Agreement which is against any of the Sellers who are due to receive Earn-out Consideration and that has been duly notified by the Purchaser to the relevant Sellers' Representatives or the Warrantors (as the case may be) in accordance with this Agreement, but which is not a Resolved Claim as at the Earn-out Consideration Completion Date.

"Paying Agent Agreements" means:

- (a) the paying agent agreement for paying agency services to be entered into prior to Completion between (1) [***], (2) the FME Shareholders' Representative, (3) the Investor Sellers' Representative, (4) the Institutional Sellers' Representative, (5) the Purchaser and (6) the Company, together with the paying agent fee letter relating to such agreement; and
- (b) the escrow agreement for escrow services in respect of the Investors Holdback Amount and FME Holdback Amount to be entered into prior to Completion between (1) [***], (2) the Company, (3) the Purchaser, (4) the FME Shareholders' Representative, (5) the Investor Sellers' Representative and (6) the Institutional Sellers' Representative, together with the escrow fee letter relating to such agreement,

in each case, in a form reasonably acceptable to the Institutional Sellers, the FME Shareholders Representative, the Investor Sellers' Representative and the Purchaser (each a **"Paying Agent Agreement"**).

"Paying Agent Fee" means [***]% of the aggregate amount payable to [***] in respect of the matters the subject of this Agreement.

"Payment Amount" means any amount of the Earn-Out Consideration due from the Purchaser to the relevant Sellers under or in connection with this Agreement.

"Pension Scheme(s)" means the group personal pension scheme of the Company operated by [***].

"Post-Completion Management Agreement" means the management agreement to be entered into between the Purchaser, the Founder Sellers and the Company regulating the governance rights of the Founder Sellers (as managers and employees (as applicable) of the Group) in respect of the Group, which shall be on terms to be agreed between the parties to it (each acting reasonably) prior to Completion, and which shall include (among other things) provisions whereby:

- (a) the prior written consent of the Founder Sellers will be required in order for the Company (or any other Group Company) to adopt or action any of the matters set out in paragraph 8(c) of Part 1 of Schedule 10 (*Calculation of Earn-out Consideration*); and
- (b) no prior written consent of the Purchaser will be required in relation to the Company (or any other Group Company) effecting any of the matters set out in paragraph 8(d) of Part 1 of Schedule 10 (*Calculation of Earn-out Consideration*); and

- (c) the Purchaser will consult with the Founder Sellers in respect of any change to be made to the allocation of any Purchaser's EIP Recipient pursuant to the Purchaser's Employee Incentive Plan, notwithstanding that each party acknowledges as at the date of this Agreement that the draft allocations are intended by each party to be in substantially agreed form.

"Properties" means the properties leased or licensed to the Group, particulars of which are set out in Schedule 3 (*The Properties*) and the **"Property"** means any one of them.

"Prospective Client" means any person who or which was at any time during the [***] month period prior to Completion negotiating with or has been subject to any presentation or pitch by any Group Company for the provision of any Restricted Business.

"Purchaser's EIP Amount" means up to £[***] in aggregate payable to the Purchaser's EIP Recipients by the Purchaser following Completion in respect of, and in accordance with the terms of, the Purchaser's Employee Incentive Plan.

"Purchaser's EIP Recipients" means those individuals agreed between the Purchaser and the Founder Sellers as at the date of this Agreement and as set out in the Purchaser's Employee Incentive Plan (or an agreed form document referred to therein).

"Purchaser's Employee Incentive Plan" means the employee incentive plan, in the agreed form [***] in respect of the Purchaser's EIP Amount, to be established for the benefit of the Purchaser's EIP Recipients pursuant to which such persons shall, subject to the terms therein, be eligible to participate.

"Purchaser's Group" means the Purchaser and any holding company and any subsidiary and any subsidiary undertaking of the Purchaser or such companies from time to time and **"Purchaser Group Company"** means any one of them.

"Purchaser's Bank Account" means the Purchaser's bank account at [***] (and/or such other bank account(s) as the Sellers' Representatives and the Purchaser may agree in writing).

"Regulation S" in the context of the Consideration Shares and Consideration ADSs, has the common meaning given in respect of US securities law with reference to the Securities and Exchange Commission.

[***]

[***]

[***]

[***]

"Relevant Authority" means any of the UK Secretary of State for Business, Energy and Industrial Strategy (or a representative), the UK Investment Security Unit, the German Bundeskartellamt, the German Federal Ministry for Economic Affairs and Climate Action, the French Minister for Economy, the General Authority for Competition in Saudi Arabia or the Taiwan Fair Trade Commission.

"Relevant Person" has the meaning given to it in sub-clause 13.1 (*Purchaser's remedies*).

"Reserved Sum" has the meaning given to it in sub-clause 19.12(a)(ii)(A) (*Set-off*).

"Resolved Claim" means any claim under this Agreement that has been:

- (a) agreed in writing between the Purchaser and the Sellers' Representatives or the Warrantors (as the case may be) as to both liability and quantum; or
- (b) finally determined by the English courts pursuant to clause 28 (*Governing Law and jurisdiction*).

"Restricted Business" means the business of producing high quality artificial intelligence, mobile applications, websites, e-commerce, e-learning, AR/VR and software solutions, as well as 3D or graphic design and social media content including, without limitation, those activities relating to life sciences and those ancillary or incidental to or in connection with such business as carried on by the Group during the [***]-month period prior to Completion in any jurisdiction where the Group was materially active during such time or had concrete and active plans to enter as at Completion.

"Restricted Period" means the period commencing on Completion and ending [***] years from Completion.

"Restricted Person" means each of:

[***]

"RSU Award" means:

- (a) any French Award that will vest on or immediately before Completion and will result in the issue and allotment of FME Completion Shares referred to in paragraphs (e) or (g) of the definition of FME Completion Shares;
- (b) any New Award in the form of a conditional right to acquire Shares that will vest automatically (without needing to be exercised) on or immediately before Completion and will result in the issue and allotment of FME Completion Shares referred to in paragraph (h) of the definition of FME Completion Shares.

"RSU Holder" means the FME Shareholders who hold an RSU Award that is to vest on or immediately before Completion.

"Schemes" has the meaning given to it in sub-clause 35.1 (*Particulars of employees and workers*) of Schedule 4.

"Securities Act" means, in the context of the Consideration Shares and Consideration ADSs, the U.S. Securities Act of 1933, as amended.

"Security Incident" means any event having an actual adverse effect on the security of the IT Systems.

"Seller Associate" means any person with whom a Seller and/or (prior to Completion) any Group Company is either associated or connected for any Tax purpose.

"Sellers' Bank Account" means the bank account maintained by [***] as shall be notified to the Purchaser by [***] (and/or such other bank account(s) as the Sellers and the Purchaser may agree in writing).

"Sellers' Solicitors" means CMS Cameron McKenna Nabarro Olswang LLP of Cannon Place, 78 Cannon Street, London, EC4N 6AF, United Kingdom.

"Sellers' Representatives" means, collectively, the FME Shareholders' Representative, the Investor Sellers' Representative and the Institutional Sellers' Representative.

"Sellers' Upfront Consideration" means the Upfront Base Consideration, as adjusted in accordance with the Completion Allocation Schedule after inserting the Actual Cash, Actual Debt and the Actual Working Capital amounts set out in the Completion Accounts and reflecting (if applicable) any increase or reduction to the Upfront Base Consideration as a result of the Actual Adjustment Amount, in respect of all Completion Fully-Diluted Shares held or to be held by the Sellers.

"Senior Employee" means:

- (a) each of the Key Employees; and
- (b) any other employee of or consultant to any Group Company whose fees and/or emoluments exceed £[***] (or the equivalent amount in local currency in respect of each of the Group Companies) per annum at the relevant time.

"Shareholder Documents" means:

- (a) the Share Purchase Agreement dated [***] between (1) the Purchaser (2) the Sellers and (3) the Company (all such terms as defined therein);
- (b) the Subscription Agreement dated [***] between (1) the Investors; (2) the Founders and (3) InstaDeep Limited (all such terms as defined therein);
- (c) the Amended and Restated Shareholders' Agreement dated [***] between (1) the New Investors; (2) the Founders; (3) the Existing Shareholders and (4) the Company (all such terms as defined therein); and
- (d) the 2022 [***] SPA.

"Share Purchase Options" means the following options granted by [***] to purchase Ordinary Shares (registered in [***] name as at the date of this Agreement):

- (a) an option granted on [***] to [***] to purchase from [***] [***] Ordinary Shares at a purchase price of £[***] per Share;
- (b) an option granted on [***] to [***] to purchase from [***] [***] Ordinary Shares at a purchase price of £[***] per Share; and
- (c) an option granted on [***] to [***] to purchase from [***] [***] Ordinary Shares (out of which [***] Ordinary Shares were vested as of the date when [***] ceased to be an employee of the relevant Group Company) at a purchase price of £[***] per Share.

"Shares" means the shares in the capital of the Company, consisting of the Ordinary Shares, Class A Shares, Class B Shares and Employee Shares.

"Signing Allocation Schedule" means the schedule, in the agreed form, setting out, amongst other matters, the details of the Sellers' residential addresses and country of residence, the Sellers' holdings of the Shares and the draft allocation of the Consideration payable to each of them as prepared, and based on information known, at the date of this Agreement.

"Signing Disclosure Letter" means the letter of the same date as this Agreement, in the agreed form, from the Warrantors to the Purchaser delivered immediately prior to the execution of this Agreement, disclosing matters that are exceptions to the Warranties given at the date of this Agreement, together with all documents annexed to it.

[***]

[***]

[***]

[***]

"Stand-alone Accounts" means the audited balance sheet as at the Accounts Date and the audited income statement for the financial period ended on the Accounts Date in each case of each Group Company (including all documents required by Applicable Law to be annexed to them for that period).

"Stock Option Plan" means the InstaDeep Ltd Share Option Plan, an employees' share scheme established by the directors of the Company on [***] (as amended), and each of the share options granted under it to employees of the Group.

"subordinate legislation" has the meaning set out in Section 21(1), Interpretation Act 1978.

"subsidiary" has the meaning set out in Section 1159, CA2006.

"subsidiary undertaking" has the meaning set out in Section 1162, CA2006.

"Surviving Provisions" means the provisions of clause 1.1 (*Definitions and interpretation*), clause 19 (*General*) (save for sub-clauses 19.5 (*Effect of Completion*) and 19.8 (*Further assurance*)), clause 20 (*Announcements*), clause 21 (*Costs and expenses*), clause 23 (*Payments*), clause 24 (*Notices*) and clause 28 (*Governing law and jurisdiction*).

"Systems Data" means the digital data (including personal and non-personal data) stored, processed, retrieved or transmitted by any element of the IT Systems.

"Target Cash Balance" means £[***].

"Target Debt Balance" means £[***].

"Target Working Capital" means £[***].

"Tax Claim" has the meaning given to it in the Tax Schedule.

"Tax Covenant" means the covenant given by the Warrantors under Part 3 of the Tax Schedule.

"Tax Schedule" means the provisions of Schedule 6 (*Tax Schedule*).

"Tax Warranties" means the warranties set out in paragraph 2 of part 2 of the Tax Schedule and the warranties set out at paragraph 36 of Schedule 4 insofar as any breach of such warranties would give rise to a claim for Tax and **"Tax Warranty"** means any one of them.

"Taxation" has the meaning given to it in the Tax Schedule.

"Third Party Claim" has the meaning set out in clause 15 (*Purchaser's conduct of Third Party Claims*).

"Total Earn-out Value" means £200,000,000, being the maximum aggregate amount that the Sellers would be entitled to receive pursuant to the Earn-out in the event that all Milestones were satisfied in accordance with the terms of this Agreement but for any Investor Seller's election to waive entitlement to [***]% of their pro rata proportion of such amount pursuant to sub-clause 4.3.

"Transaction" means the transactions contemplated by this Agreement.

"Transaction Document" means this Agreement, the Signing Disclosure Letter, the Completion Disclosure Letter, any document in the agreed form, and any other agreement entered into pursuant to the foregoing.

"Transaction Expenses" means costs, expenses, fees and other payments made to advisors by any Group Company in connection with the Transaction.

"Tunisia Completion" has the meaning given set out in sub-clause 2.11.

"Tunisian Sellers" means those Sellers that will, as at Completion, be resident or domiciled in Tunisia.

"TUPE Regulations" means the Transfer of Undertakings (Protection of Employment) Regulations 1981 (SI 1981/1794) and/or, as the case may be, the Transfer of Undertakings (Protection of Employment) Regulations 2006 (SI 2006/246).

"Upfront Base Consideration" means the sum of £[***] per share.

"US FME Shareholders" means those FME Shareholders who are a "U.S. person" (as such term is defined in Regulation S) under the Securities Act, the final list of which will be delivered by the FME Shareholders' Representative to the Purchaser no later than [***] Business Days prior to Completion.

"US FME Shareholders Upfront Cash Completion Payment" means the Estimated Sellers' Upfront Consideration in respect of the Consideration Shares held by the relevant US FME Shareholders.

"VWAP Value" means \$[***], being the Bloomberg [***] calendar day volume-weighted average price of the Purchaser's shares listed on NASDAQ (over that [***] calendar period not on a daily basis), such period ending on [***].

"Warranties" means the Non-Tax Warranties and the Tax Warranties, and **"Warranty"** means any one of them.

"Warrantors" means the Founder Sellers.

"Warranty Claim" means a claim by the Purchaser against the Warrantors for breach of any of the Warranties.

"Working Capital" means the aggregated amount of:

- (a) trade receivables, less any loss allowance (bad debt allowance); and
- (b) all other current receivables, deferred revenue, other current assets, prepaid expenses (including receivables relating to taxes other than income taxes), financial deposit and accrued interests on the financial deposits to the extent not included in Cash or Debt;
less:
 - (i) trade payables;
 - (ii) prepayments received;
 - (iii) all other current provisions and accruals other than income taxes to the extent not included in Debt and separately treated in this definition;
 - (iv) any provisions, accruals or liabilities relating to contractual bonuses (including the commission bonuses payable to [***] and to [***]) which refers to the period ending on the Effective Time including any social security contribution;
 - (v) any provisions, accruals or liabilities relating to the 13th salary including any social security contribution;
 - (vi) any provisions, accruals or liabilities relating to employee benefits such as unused holidays or overtime including any social security contribution which are not above the amounts legally authorized to carry-over or which are related to the legal holiday entitlement for the current year;
 - (vii) all other current payables (including liabilities relating to taxes other than income taxes), to the extent not included in Debt,

in each case to which the Company or any of the Subsidiaries is beneficially entitled as at the Effective Time, calculated on a consolidated basis in accordance with the accounting principles, policies, standards, practices, evaluation rules and estimation techniques specified in Part 2 of Schedule 9 (*Completion Accounts*). An illustrative detailed mapping on account basis designated as "Working Capital" is outlined in Part 3 of Schedule 9.

"Working Time Regulations" means the Working Time Regulations 1998 (SI 1998/1833).

"W&I Cost" means £[***], being [***]% of the aggregate amount payable in respect of the W&I Policy, including the insurance premium, brokerage costs, underwriting costs and insurance premium tax.

"W&I Insurer" means the insurer for the W&I Policy being principally [***], together with [***], [***] and joint insurers, [***], as set out under the W&I Policy.

"W&I Policy" means the warranty and indemnity insurance policies in the agreed form with policy number [***] and [***], issued by the W&I Insurer in favour of the Purchaser on the date of this Agreement and relating to claims under this Agreement.

"W&I Policy Excerpt" means an excerpt of the W&I Policy showing no subrogation rights against the Warrantors except in the case of fraud, dishonesty or wilful misconduct.

1.2 In this Agreement:

- (a) words in the singular include the plural and vice versa and words in one gender include any other gender;
- (b) a reference to a statute or statutory provision includes:
 - (i) any subordinate legislation;
 - (ii) any repealed statute or statutory provision which it re-enacts (with or without modification); and
 - (iii) any statute, statutory provision or subordinate legislation which modifies, consolidates, re-enacts or supersedes it,provided such subordinate legislation, re-enactment, statute or statutory provision came into force before the date of this Agreement;
- (c) a reference to:
 - (i) a **"party"** means each person as set out at the head of page 1 (save for InstaDeep), a reference to "parties" means all of the parties to this Agreement (save for InstaDeep) and, upon any succession or permitted assignment, a reference to any party shall be deemed to include a reference to that party's successors in title or permitted assigns;
 - (ii) a **"person"** includes any individual, firm, corporation, body corporate, association or partnership, trust, unincorporated organisation, employee representative body, government or state or agency or department thereof, executors, administrators or successors in title (whether or not having a separate legal personality);
 - (iii) clauses and schedules are to clauses and schedules of this Agreement and references to sub-clauses and paragraphs are references to sub-clauses and paragraphs of the clause or schedule in which they appear;
 - (iv) any provision of this Agreement is to that provision as amended in accordance with the terms of this Agreement;
 - (v) any document being **"in the agreed form"** means in a form which has been agreed in writing by the parties (or by their respective solicitors on their behalf) on or before the date of this Agreement;
 - (vi) any English legal term for any action, remedy, method of judicial proceeding, legal document, legal status, legal concept, state of affairs or thing or references to any English body, organisation, court or official shall in each case in respect of any jurisdiction other than England or any body corporate incorporated in any such jurisdiction, be deemed to refer to and include that which most approximates in that jurisdiction to the English legal term, body, organisation, court or official;
 - (vii) any reference to any English statute, statutory provision or EU derived law applicable in England shall in each case in respect of any jurisdiction other than England or a body corporate incorporated in any such jurisdiction, be deemed to include a reference to all Applicable Law relating to the same subject matter as that English statute, statutory provision or EU derived law; and
 - (viii) references to times of the day are to local time in the relevant jurisdiction unless otherwise stated;
- (d) save as expressly defined or otherwise set out in sub-clause 1.1 (*Definitions and interpretation*) or this sub-clause 1.2 (*Definitions and interpretation*) or in any other provision of this Agreement, words and expressions which are defined in the CA2006 shall have the meaning attributed to them in the CA2006 when used in this Agreement;
- (e) **"sterling"** and the sign **"£"** means pounds sterling in the currency of the United Kingdom;
- (f) **"Euros"** and the sign **"€"** means euros in the currency of the European Union;

- (g) **"UK"** means the United Kingdom of Great Britain and Northern Ireland;
- (h) the table of contents and headings are for convenience only and shall not affect the interpretation of this Agreement;
- (i) general words shall not be given a restrictive meaning:
 - (i) if they are introduced by the word "other" or "including" or similar words by reason of the fact that they are preceded by words indicating a particular class of act, matter or thing; or
 - (ii) by reason of the fact that they are followed by particular examples intended to be embraced by those general words;
- (j) where any statement is qualified by the expression **"so far as the Warrantors are aware"** or **"to the best of the Warrantors' knowledge and belief"** or any similar expression, it shall be deemed to refer to the actual awareness, knowledge or belief of the Warrantors having made due and careful enquiry of:
 - (i) [***];
 - (ii) [***] in respect of InstaDeep Dubai (branch) and InstaDeep Abu Dhabi (branch);
 - (iii) [***] in respect of InstaDeep South Africa (branch);
 - (iv) [***] (only in respect of the Non-Tax Warranties at paragraphs 35 to 40 (*Employment*) and paragraphs 41 to 43 (*Pensions*) of Schedule 4);
 - (v) [***] (only in respect of the Non-Tax Warranties at paragraphs 9 to 13 (*Accounts*), paragraphs 16 to 17 (*Insurance*), paragraphs 35 to 40 (*Employment*), paragraphs 41 to 43 (*Pensions*), paragraph 18 (*Contracts and commitments*), paragraph 19 (*Trading partners*) and paragraphs 24 to 25 (*Assets*) of Schedule 4);
 - (vi) [***] (only in respect of the Non-Tax Warranties at paragraphs 26 to 29 (*Intellectual Property*) and paragraph 30 (*Information technology*) of Schedule 4);
 - (vii) [***] (only in respect of the Non-Tax Warranties at paragraph 18 (*Contracts and commitments*), paragraph 19 (*Trading partners*), paragraph 21 (*Competition and trade regulation law*), paragraph 23 (*Litigation*), paragraphs 26 to 29 (*Intellectual Property*) and paragraph 34 (*Data Protection*) of Schedule 4);
 - (viii) [***] (only in respect of the Non-Tax Warranties at paragraphs 26 to 29 (*Intellectual Property*) of Schedule 4); and
 - (ix) the following individuals only in respect of (i) the Non-Tax Warranties at paragraphs 9 to 13 (*Accounts*), paragraphs 35 to 40 (*Employment*) and paragraphs 41 to 43 (*Pensions*) of Schedule 4; and (ii) the Tax Warranties:
 - (A) [***] only in respect of the Company;
 - (B) [***] only in respect of InstaDeep SAS;
 - (C) [***] only in respect of InstaDeep Dubai (branch) and InstaDeep Abu Dhabi (branch);
 - (D) [***] only in respect of InstaDeep Nigeria Limited;
 - (E) [***] only in respect of InstaDeep LLC;
 - (F) [***] only in respect of InstaDeep Tunisia;
 - (G) [***] only in respect of InstaDeep South Africa (branch); and
 - (H) [***] only in respect of InstaDeep Deutschland GmbH;
 - (x) [***] (only in respect of the Tax Warranties in respect of InstaDeep SAS).
- (k) where any liability or obligation is undertaken by two or more parties the liability or obligation of each of them shall be several (and not joint and several), unless expressly stated to the contrary;
- (l) for the purposes only of the membership requirement contained in subsections 1159(1)(b) and (c), CA 2006, shares registered in the name of a person (or its nominee) by way of security or in connection with the taking of security shall be treated as held by the person providing the security and shares held by a person as nominee for another shall be treated as held by the other;

- (m) references in any Warranty to any monetary sum expressed in a sterling amount shall, where such sum is referable in whole or part to a particular jurisdiction, be deemed to be a reference to an equivalent amount in the local currency of that jurisdiction translated at the Exchange Rate as at the date on which the relevant Warranty was given;
- (n) where it is necessary to determine whether a monetary limit or threshold set out in clause 14 (*Limitations on liability*) has been reached or exceeded (as the case may be) and the value of the relevant claim or any of the relevant claims is expressed in a currency other than sterling, the value of each such claim shall be translated into sterling at the Exchange Rate on the date of receipt by the Warrantors of written notification from the Purchaser in accordance with clause 14 (*Limitations on liability*) of the existence of such claim; and
- (o) where any provision is qualified or phrased by reference to the ordinary course of business, such reference shall be construed as meaning the customary course of trading for the business of the Group in the country concerned.

2. Conditions precedent

2.1 Except for the provisions of this clause 2 (Conditions precedent) and the following provisions:

- (a) clause 1.1 (*Definitions and interpretation*);
- (b) sub-clause 3.6 (*Sale and purchase*);
- (c) clause 6 (*Pre Completion obligations*);
- (d) sub-clause 7.5 (*Completion*);
- (e) clause 10 (*Warranties*);
- (f) clause 19 (*General*) save for sub-clauses 19.5 (*Effect of Completion*) and 19.8 (*Further assurance*);
- (g) clause 20 (*Announcements*);
- (h) clause 21 (*Costs and expenses*);
- (i) clause 23 (*Payments*);
- (j) clause 24 (*Notices*); and
- (k) clause 28 (*Governing law and jurisdiction*),

which shall all be effective from the date of this Agreement notwithstanding this sub-clause 2.1 (*Conditions precedent*), all other provisions of this Agreement and Completion are in all respects conditional upon satisfaction or waiver of the Conditions in accordance with this clause 2 (*Conditions precedent*):

2.2 The Conditions are that:

- (a) to the extent that the Transaction amounts to a trigger event under section 5(1) of the UK National Security and Investment Act 2021 ("NSIA"), notification having been accepted by or on behalf of the Secretary of State for Business, Energy and Industrial Strategy (or a representative) (the "**Secretary of State**"), and the Secretary of State for the purposes of the NSIA either:
 - (i) notifies the Purchaser that no further action will be taken by the Secretary of State in relation to the Transaction; or
 - (ii) makes a final order permitting the Transaction to proceed subject only to such remedies or requirements that are in all respects acceptable to the Purchaser and the Sellers (and to the extent relevant, all conditions, provisions or obligations contained in such final order which are necessary for completion of the Transaction having been satisfied or complied with), and such order is not revoked or varied before Completion;
- (b) to the extent that the Transaction requires a mandatory notification to the German Federal Cartel Office (*Bundeskartellamt*), that the German Federal Cartel Office:
 - (i) has not announced within the one month period a decision to open in-depth review proceedings in relation to the Transaction (*Hauptprüfverfahren*); or
 - (ii) has explicitly stated to not oppose the Transaction;
- (c) to the extent that the Transaction requires a mandatory notification to the German Federal Ministry for Economic Affairs and Climate Action (*Bundesministerium für Wirtschaft und Klimaschutz*, "**BMWK**"), the Transaction having been approved, or

being deemed to have been approved, by the BMWK, or any stand-still obligation or prohibition to complete the Transaction having otherwise fallen away;

- (d) to the extent that the Transaction requires a mandatory notification to the French Minister for Economy (*Ministre de l'Economie, des Finances et de la Souveraineté Industrielle et numérique*, "**Minister for Economy**") under Articles L.151-3 et seq. and R. 151-3 et seq. of the French Monetary and Financial Code:
 - (i) the Minister for Economy having concluded that prior approval of the Transaction is not required under foreign direct investment screening regulation as not all of the conditions for screening have been met, or
 - (ii) the Minister for Economy having concluded that the Transaction is authorised (with or without condition(s)); or
 - (iii) any stand-still obligation or prohibition to complete the Transaction having otherwise fallen away;
- (e) to the extent that the Transaction requires a mandatory merger notification to the General Authority for Competition in Saudi Arabia ("**GAC**"), the Transaction having been approved, or being deemed to have been approved, by the GAC, or any stand-still obligation or prohibition to complete the Transaction having otherwise fallen away;
- (f) to the extent that the Transaction requires a mandatory merger notification to the Taiwan Fair Trade Commission ("**TFTC**"), the Transaction having been approved, or being deemed to have been approved, by the TFTC, or any stand-still obligation or prohibition to complete the Transaction having otherwise fallen away; and
- (g) the Central Bank of Tunisia having provided its authorisation(s), approval(s) or equivalent confirmation evidencing that the Central Bank of Tunisia has no objections to:
 - (i) the exercise by the Tunisian Sellers of their options granted under the Stock Option Plan, in each case on or prior to Completion;
 - (ii) the sale by the Tunisian Sellers of their respective Shares on terms and conditions set out in this Agreement;
 - (iii) the receipt by the Tunisian Sellers of their respective Consideration ADSs on terms and conditions set out in this Agreement; and
 - (iv) any other matters as may be submitted to it by the relevant Tunisian Sellers and that are necessary in order to proceed to Completion under this Agreement

together, the "**CBT Condition**".

2.3 The Purchaser shall (so far as it lies within its powers) use all reasonable endeavours to procure that the Conditions are satisfied as soon as practicable and, in any event, not later than 31 July 2023 (or such later date as the Purchaser and the Sellers may agree), including agreeing, accepting and implementing any commercially reasonable undertakings, commitments, measures and other steps (each a "Commitment") necessary to avoid or negate any action (including any order, decision, judgment or injunction) that would otherwise have the effect of preventing the Conditions from being satisfied. The Purchaser shall not accept or agree to any undertaking, commitment, divestment, condition, obligation, measure, modification or other step in connection with satisfying any of the Conditions that requires any amendment, variation or modification to the terms of this Agreement, without the prior written approval of the Sellers' Representatives.

2.4 The Purchaser shall for the purposes of clause 2.3 above:

- (a) prepare, or procure preparation of, in a form reasonably acceptable to the Sellers, the relevant notifications or filings required in order to fulfil the Conditions as soon as possible after the date of this Agreement;
- (b) promptly deal with all requests and enquiries from any Relevant Authority and provide all information which is required by any of them in connection with satisfying the Conditions;
- (c) promptly notify the Sellers and provide copies or, in the case of non-written communications, details, of any communications with a Relevant Authority relating to any such consent, approval or action to fulfil the Conditions;
- (d) provide the Sellers with final drafts of all submissions, notifications, filings and other communications to any Relevant Authority at such time as will allow the Sellers a reasonable opportunity to provide comments and for the Purchaser, in its reasonable

- discretion, to take account of any comments of the Sellers on such drafts prior to their submission;
- (e) communicate with any Relevant Authority in respect of the Transaction to the extent reasonably possible only after prior consultation with the Sellers, taking into account any reasonable comments and requests of the Sellers and provide the Sellers with copies of submissions, notifications or filings in the form submitted or sent or, in the case of non-written communications, provide details of such communications;
 - (f) where permitted by the Relevant Authority and to the extent circumstances allow, give reasonable notice of, and allow persons nominated by the Sellers to attend, all meetings, and to participate in all material telephone or other conversations;
 - (g) regularly review with the Sellers the progress of the notifications or filings, including, where necessary, seeking to identify appropriate responses to address any concerns identified by any Relevant Authority and discuss with the Sellers the scope, timing and tactics of any proposed responses with a view to obtaining satisfaction of the Conditions at the earliest reasonable opportunity.
- 2.5 The Purchaser shall be responsible for paying any filing, administrative or other fees levied by any Relevant Authority and/or the Central Bank of Tunisia for the purpose of satisfying the Conditions.
- 2.6 Each of the Purchaser and the Sellers' Representatives shall notify the other in writing of any circumstance, event, fact or matter which will or may prevent fulfilment of the Conditions as soon as such circumstance, event, fact or matter comes to their attention.
- 2.7 The Sellers agree in connection with the Conditions that they will notify the Purchaser as soon as reasonably practicable of any material written communications they receive from any Relevant Authority in relation to such application, submission or information, promptly provide the Purchaser with a copy of any such communication and deal with any requests or enquiries from the relevant authority in consultation with the Purchaser.
- 2.8 The Sellers shall co-operate fully in all actions necessary to procure the satisfaction of the Conditions (excluding the CBT Condition) including (but not limited to) the provision by the Sellers of all information reasonably necessary to make any notification or filing in order to satisfy the Conditions.
- 2.9 Nothing in this Agreement shall require either party to disclose to or receive from the other any information:
- (a) which the disclosing party is prohibited from disclosing or the receiving party is prohibited from receiving by Applicable Law;
 - (b) where such disclosure would result in the loss of any privilege that subsists in relation to such information, including legal professional privilege; or
 - (c) which the disclosing party or its affiliated persons reasonably considers to be commercially or competitively sensitive or where disclosure to the other party would reasonably be expected to have a material adverse effect on the disclosing party's legitimate business interests, in which case the disclosing party shall, to the extent permitted by Applicable Law, disclose the relevant information to the other party on an outside counsel basis (acting reasonably in identifying such information) and provide a non-confidential version of such information to the other party.
- 2.10 Subject to sub-clause 2.11 the Conditions are not satisfied in full by the date specified in clause 2.3 then the Purchaser, the Institutional Sellers and the Sellers Representatives (excluding the Institutional Sellers' Representative) may agree to:
- (a) waive any unsatisfied Condition (save that such waiver shall not act as a waiver of the Purchaser's or the Sellers' (as applicable) right to claim for breach of this Agreement);
 - (b) extend the period for satisfying any unsatisfied Condition to a date [***] days after that date (in which case the provisions of this sub-clause shall also apply as if the revised date were the date specified in sub-clause 2.3 (*Conditions precedent*)), provided that such period for satisfaction shall not extend beyond [***] of the date of this Agreement; or
 - (c) terminate this Agreement (other than the Surviving Provisions and the provisions of this sub-clause 2.10(c) (*Conditions precedent*)) by notice in writing, in which event:
 - (i) the Surviving Provisions and the provisions of this sub-clause 2.10(c) (*Conditions precedent*) shall continue to apply;
 - (ii) no party shall have any claim under this Agreement of any nature whatsoever against any other party except in respect of any rights, liabilities and

obligations which have accrued before termination or which accrue under any of the Surviving Provisions or under this sub-clause 2.10(c) (*Conditions precedent*); and

- (iii) except as referred to in this sub-clause 2.10(c) (*Conditions precedent*), all rights, liabilities and obligations of the parties under this Agreement shall cease with immediate effect.

2.11 If the Conditions (other than the CBT Condition) have been satisfied in full (or otherwise waived pursuant to sub-clause 2.10), the Purchaser, the Institutional Sellers and the Sellers' Representatives (excluding the Institutional Sellers' Representative) may agree to:

- (a) proceed to Completion in accordance with the terms of this Agreement only in respect of those Sellers who are not Tunisian Sellers, notwithstanding that the CBT Condition has not been satisfied; and
- (b) extend the period for satisfying the CBT Condition to a date agreed between the Purchaser and the FME Shareholders' Representative,

in which case the completion of the sale and purchase of the Completion Shares held by the Tunisian Sellers (the "**Tunisia Completion**") will occur in respect of the Completion Shares held by Tunisian Sellers only once and on such date, falling no later than 10 Business Days after the CBT Condition has been satisfied in full, as the Purchaser will notify to the FME Shareholders' Representative and the Investor Sellers' Representative (the "**Tunisia Completion Date**") (and the provisions of this Agreement shall be deemed to have been amended, including that payment of the relevant Consideration shall only become due and payable by the Purchaser on the Tunisia Completion Date. In order to give effect to this sub-clause 2.11, the Purchaser shall transfer the relevant Upfront Consideration amount due to the Tunisian Sellers (which shall include, as applicable, their relevant proportion of: (i) [***] and (ii) the Holdback Amount plus or minus, if known at the relevant time, any applicable pro-rata Consideration Increase or Consideration Reduction finally determined in accordance with this Agreement) to the Sellers' Bank Account at least 2 Business Days prior to the Tunisia Completion Date and, if applicable, [***] shall, in accordance with the Paying Agent Agreements, hold in escrow an amount equal to the relevant proportion of [***] and the Holdback Amount in respect of the Completion Shares held by the Tunisian Sellers until such time as this is due to be released in accordance with clause 5.2.

2.12 In the event that the relevant parties agree to proceed to Completion and, if applicable, agree to extend the period for satisfying the CBT Condition, in each case pursuant to sub-clause 2.11, each Tunisian Seller irrevocably undertakes to the Purchaser that, for as long as such Tunisian Seller remains the registered holder of the Shares after Completion but before the Tunisia Completion, such Tunisian Seller shall:

- (a) hold the Shares and any dividends and other moneys or assets paid or distributed in respect of them and all rights arising out of or in connection with them from Completion in trust for the Purchaser;
- (b) deal with the Shares and all such dividends, distributions and rights as the Purchaser may direct from Completion until the date on which the Purchaser or its nominee is entered in the register of members of the Company as the holder of the Shares; and
- (c) unless otherwise agreed with the Purchaser, not exercise or otherwise deal with any Options held by them until the CBT Condition has been satisfied in full.

3. Sale and purchase

- 3.1 Subject to the provisions of this Agreement, the Sellers shall sell, and the Purchaser shall purchase, the Completion Shares with effect from Completion.
- 3.2 The Completion Shares shall be sold with the benefit of all rights attaching to or accruing to them as at the date of Completion, including all dividends or other distributions declared, paid or made by the Company on or after the date of Completion.
- 3.3 Subject to sub-clause 2.11, the Purchaser shall not be obliged to complete the purchase of the Completion Shares unless the sale and purchase of all the Completion Shares is completed simultaneously.
- 3.4 Each of the Sellers hereby irrevocably and unconditionally waives all rights of pre-emption or similar rights over any of the Completion Shares conferred on him by either the articles of association of the Company or in any other way, in each case in connection with the Transaction only.
- 3.5 Each of the Sellers hereby irrevocably and unconditionally waives any and all claims they have (in their capacity as shareholders of the Company only) against any Group Company as at Completion. Each Seller, in respect of such Seller's commercial agreements with any Group Company only (if any, as applicable), confirms as at the date of this Agreement that it is not

aware of any claims existing, threatened or pending against any Group Company. For the purposes of this clause 3.5, "awareness" shall be deemed to refer to:

- (a) in the case of [***], the actual knowledge of [***]; and
- (b) in the case of all other Sellers, the actual knowledge of that Seller (if the Seller is an individual) or, where the Seller is a body corporate, the actual knowledge of (i) the general counsel of that Seller; or (ii) if no general counsel is in place, the person heading or leading the legal function within the relevant Seller; or (iii) if no general counsel or legal role is in place, the directors of that Seller.

3.6 Each of the Sellers severally warrants to the Purchaser in respect of itself only both at the date of this Agreement and again at Completion (save that, in respect of any Completion Shares that are not also Exchange Shares, the FME Shareholders shall only warrant at Completion and save that [***] Ordinary Shares held by [***] are subject to the provisions of clauses 3.11 and 3.12) that:

- (a) the Completion Shares set out opposite that Seller's name in Schedule 1 (*The Sellers*) are fully paid up (or credited as fully paid);
- (b) in respect of the ownership of the Completion Shares:
 - (i) save for the [***] Shares that are not registrable by the Company as at the date of this Agreement pending confirmation of stamping, it is the sole legal owner of the Completion Shares set out opposite its name in Schedule 1 (*The Sellers*);
 - (ii) it is the sole beneficial owner of such Completion Shares.

3.7 Each of the Sellers severally warrants to the Purchaser in respect of itself only both at the date of this Agreement and again at Completion that:

- (a) subject to confirmation of stamping and completion of the registration of transfer by the Company in the Company's statutory books of the [***] Shares, it has and shall have pursuant to this Agreement the right to transfer the legal and beneficial title to the Completion Shares set out opposite its name in Schedule 1 (*The Sellers*) on the terms of this Agreement and without the consent of any third party and that they will be transferred free from any Encumbrance;
- (b) it has the full power and authority to enter into and perform this Agreement and each of the documents to be executed by it and delivered pursuant to this Agreement, each of which shall constitute valid and binding obligations on it; and
- (c) he is not bankrupt, has not proposed a voluntary arrangement nor has made or proposed any arrangement or composition with his creditors or any class of his creditors.

3.8 The Purchaser warrants to the Sellers both at the date of this Agreement and again at Completion that:

- (a) It has the full power and authority to enter into and perform this Agreement and each of the documents to be executed by it and delivered pursuant to this Agreement, each of which shall constitute valid and binding obligations on it;
- (b) otherwise than as contemplated in clause 2 above, it is not required to obtain any consent or approval of, or give any notice to or make any registration with, any governmental or other authority in respect of the Transaction which has not been obtained or made at the date of this Agreement;
- (c) it is not bankrupt, has not proposed a voluntary arrangement nor has made or proposed any arrangement or composition with its creditors or any class of its creditors;
- (d) the execution and delivery by it of this Agreement and the performance of and compliance with their respective terms and provisions will not:
 - (i) result in a breach of any provision of the constitutional documentation of the Purchaser; or
 - (ii) conflict with or result in a breach of, or constitute a default under, any agreement or instrument to which it is a party or by which it is bound or any order, judgment or decree of any court, governmental agency or regulatory body by which it is bound; and
- (e) at Completion, it will have immediately available on an unconditional basis the necessary cash resources to meet its obligations under this Agreement.

Put and Call Arrangements

3.9 In relation to the FME Retained French Shares held, or acquired, by an FME Shareholder:

- (a) At any time within the period of [***] commencing on the date set against that FME Shareholder's name in column E4 of the table set out in Part 1 of Schedule 1, the Purchaser shall have the right to purchase all (but not some only) of those FME Retained French Shares in accordance with the terms of paragraph (c). The Purchaser may exercise this right by serving a written notice on the FME Shareholder.
- (b) In the event that the Purchaser does not exercise the right to purchase the FME Retained French Shares within the [***] day period referred to in paragraph (a) then, at any time within the period of [***] days commencing one day after the end of the [***] day period referred to in paragraph (a), the FME Shareholder shall have the right to sell all (but not some only) of their FME Retained French Shares in accordance with the terms of paragraph (c). The FME Shareholder may exercise this right by serving a written notice on the Purchaser.
- (c) Upon any service of a notice by the Purchaser on the FME Shareholder in accordance with paragraph (a), or by the FME Shareholder on the Purchaser in accordance with paragraph (b), a legally binding irrevocable and unconditional agreement shall immediately arise for the sale and purchase of the relevant FME Retained French Shares. Under the terms of that agreement, the FME Shareholder shall be bound to sell and the Purchaser shall be bound to purchase the FME Retained French Shares for the following Consideration per each FME Retained French Share (its pro rata share only of):
 - (i) the Upfront Consideration; and
 - (ii) the Contingent Consideration (calculated and payable in accordance with Schedule 10 and always subject to the rights of the Purchaser pursuant to sub-clause 19.12 (*Set-off*)).
- (d) The sale and purchase of the FME Retained French Shares shall complete on such date (and time) as is determined by the Purchaser, such date not to be more than [***] days after the service of the notice (as the case may be) by the Purchaser on the FME Shareholder in accordance with paragraph (a) or by the FME Shareholder on the Purchaser in accordance with paragraph (b). On the completion of the sale and purchase of the FME Retained French Shares:
 - (i) the FME Shareholder shall deliver to the Purchaser a duly executed transfer of the FME Retained French Shares held by them in favour of the Purchaser; and
 - (ii) the Purchaser shall pay to the FME Shareholder the Consideration (as set out in paragraph (c)) for those FME Retained French Shares.
- (e) If the FME Shareholder fails to comply with paragraph (d), the Purchaser is hereby irrevocably authorised to execute, or to authorise and instruct such person as it thinks fit to execute, any necessary transfer, indemnity or certificate on behalf of the FME Shareholder and, against receipt by the Company of the Consideration payable for the FME Retained French Shares, to deliver any such transfer, indemnity or certificate to the Purchaser. The Company shall hold the Consideration on trust for the FME Shareholder without any obligation to pay interest.

3.10 In relation to any FME 2024 French Shares acquired by an FME Shareholder:

- (a) At any time within the period of [***] days commencing on [***], the Purchaser shall have the right to purchase all (but not some only) of those FME 2024 French Shares in accordance with the terms of paragraph (c). The Purchaser may exercise this right by serving a written notice on the FME Shareholder.
- (b) In the event that the Purchaser does not exercise the right to purchase the FME 2024 French Shares within the [***] day period referred to in paragraph (a) then, at any time within the period of [***] days commencing one day after the end of the [***] day period referred to in paragraph (a), the FME Shareholder shall have the right to sell all (but not some only) of their FME 2024 French Shares in accordance with the terms of paragraph (c). The FME Shareholder may exercise this right by serving a written notice on the Purchaser.
- (c) Upon any service of a notice by the Purchaser on the FME Shareholder in accordance with paragraph (a), or by the FME Shareholder on the Purchaser in accordance with paragraph (b), a legally binding, irrevocable and unconditional agreement shall immediately arise for the sale and purchase of the relevant FME 2024 French Shares. Under the terms of that agreement, the FME Shareholder shall be bound to sell and the Purchaser shall be bound to purchase the FME 2024 French Shares for the following Consideration per each FME 2024 French Shares (its pro rata share only of):

- (i) the Sellers' Upfront Consideration; and
 - (ii) the Contingent Consideration (calculated and payable in accordance with Schedule 10 and always subject to the rights of the Purchaser pursuant to sub-clause 19.12 (*Set-off*)).
- (d) The sale and purchase of the FME 2024 French Shares shall complete on such date (and time) as is determined by the Purchaser, such date not to be more than [***] days after the service of the notice (as the case may be) by the Purchaser on the FME Shareholder in accordance with paragraph (a) or by the FME Shareholder on the Purchaser in accordance with paragraph (b). On the completion of the sale and purchase of the FME 2024 French Shares:
- (i) the FME Shareholder shall deliver to the Purchaser a duly executed transfer of the FME 2024 French Shares held by them in favour of the Purchaser; and
 - (ii) the Purchaser shall pay to the FME Shareholder the Consideration (as set out in paragraph (c)) for those FME 2024 French Shares.
- (e) If the FME Shareholder fails to comply with paragraph (d), the Purchaser is hereby irrevocably authorised to execute, or to authorise and instruct such person as it thinks fit to execute, any necessary transfer, indemnity or certificate on behalf of the FME Shareholder and, against receipt by the Company of the Consideration payable for the FME 2024 French Shares, to deliver any such transfer, indemnity or certificate to the Purchaser. The Company shall hold the Consideration on trust for the FME Shareholder without any obligation to pay interest.
- (f) Notwithstanding any other provisions of this Agreement, any notice or other document which the Purchaser wishes to deliver to the FME Shareholders or any of them pursuant to this clause 3.10 may be delivered to them by being delivered to the FME Shareholders' Representative in accordance with the provisions set out in clause 24 (*Notices*).

Share Purchase Options

- 3.11 It is acknowledged that [***] has granted the Share Purchase Options over, in total, [***] of the Ordinary Shares registered in [***] name (out of which [***] Ordinary Shares have vested) (the "**Applicable Ordinary Shares**"). [***] hereby agrees that:
- (a) [***] will procure that the vested Share Purchase Options are exercised in full on or before Completion (or, to the extent that they are not exercised, will procure that they lapse); and
 - (b) [***] will procure that, following the transfer of the Applicable Ordinary Shares to the holders of the Share Purchase Options, each such holder is entered as the legal owner of the Applicable Ordinary Shares in the Company's register of members no later than immediately before Completion.
- 3.12 The Purchaser and the Founders will procure that the exercise price owed to [***] in consideration for the transfer of the Applicable Ordinary Shares pursuant to the Share Purchase Options will be paid to [***] as part of the Completion funds flow, out of the consideration to be received by the holders of the Share Purchase Options from the Purchaser in respect of the sale of their respective Applicable Ordinary Shares as part of Completion.
- 3.13 Part 1, Law of Property (Miscellaneous Provisions) Act 1994 shall not apply to any disposition of the Shares made under or pursuant to this Agreement.

4. Consideration

- 4.1 The Consideration payable for each Completion Share is:
- (a) the Sellers' Upfront Consideration; plus
 - (b) the Contingent Consideration.
- 4.2 The Consideration for the Completion Shares shall be satisfied as follows:
- (a) as to the Upfront Consideration:
 - (i) by the payment to each Investor Seller of the Sellers' Upfront Consideration multiplied by the number of Completion Shares held by each Investor Seller;
 - (ii) in respect of each Non-US FME Shareholder (other than the holders of FME 2024 French Shares in respect of such FME 2024 French Shares only):
 - (A) by the payment of a cash sum comprising (i) [***]% of the Sellers' Upfront Consideration **multiplied by** the number of Completion Fully Diluted Shares held by the Non-US FME Shareholders; and (ii) such

amount as is agreed pursuant to sub-clauses 4.4 and 4.5 between the Purchaser and the FME Shareholders' Representative as being the FME Shareholders' Transaction Tax Liability,

(B) subject to any further adjustments as required to account for any [***] in accordance with this Agreement, by the allotment by the Purchaser to the Depository of the aggregate number of Consideration Shares and delivery by the Depository to each Non-US FME Shareholder of such number of Consideration ADSs as is set out in the Completion Allocation Schedule and in accordance with the calculations in clause 7.3(d); and

(iii) in respect of the US FME Shareholders and the holders of FME 2024 French Shares (in respect of such FME 2024 French Shares only), subject to any further adjustments as required to account for any [***] in accordance with this Agreement, by the payment to each such person of the Sellers' Upfront Consideration **multiplied by** the number of Completion Fully Diluted Shares held by such person as set out in the Completion Allocation Schedule;

(b) as to the Contingent Consideration:

(i) subject to sub-clause 4.3, by the payment to the Investor Sellers of the Investor Sellers' Upfront Contingent Cash Consideration; and

(ii) by the payment to each FME Shareholder of their respective pro rata proportion (as set opposite his or her name in the Completion Allocation Schedule) of the Earn-out Consideration on the Earn-out Consideration Completion Date, in each case, in accordance with clause 23 (*Payments*) and subject to Schedule 10 (*Calculation of Earn-out Consideration*) and subject always to the rights of the Purchaser pursuant to sub-clause 19.12 (*Set-off*).

4.3 Each Seller who shall receive Investor Sellers' Upfront Contingent Cash Consideration pursuant to the terms of this Agreement hereby waives any and all entitlement to receive any Earn-out Consideration that may otherwise be payable to such Seller pursuant to the terms of this Agreement.

FME Shareholders' Transaction Tax Liability

4.4 As soon as practicable after the date of this Agreement, the FME Shareholders' Representative, having taken professional advice, shall deliver to the Purchaser its methodology for estimating the FME Shareholders' Transaction Tax Liability (the "**Proposed Methodology**"), providing supporting evidence and information so as to allow the Purchaser to undertake a review of the Proposed Methodology. The Purchaser shall review the Proposed Methodology and discuss with the FME Shareholders' Representative any proposed amendments. The FME Shareholders' Representative and the Purchaser shall use all reasonable endeavours to reach agreement on the Proposed Methodology. If agreement on the Proposed Methodology cannot be reached within [***] Business Days of the date of delivery to the FME Shareholders' Representative of the first draft, any matter still in dispute may upon the direction of the Purchaser or the FME Shareholders' Representative be referred to an Independent Expert for determination. Upon agreement or determination (as the case may be), the resulting methodology shall be the agreed methodology (the "**Agreed Methodology**") for the purposes of this Agreement.

4.5 On the day that is no later than [***] Business Days prior to the Completion Date, the FME Shareholders' Representative shall deliver to the Purchaser the final Completion Allocation Schedule signed by the FME Shareholders' Representative on behalf of the FME Shareholders (prepared using the Agreed Methodology and including calculation of the FME Shareholders' Transaction Tax Liability, by reference to the FME Shareholders' Representative's reasonable estimate of the price of the Purchaser's shares listed on NASDAQ on or around the proposed Completion Date as well as the estimates and adjustment amounts contemplated by the Estimates Notice, updated with the most up-to-date information available at the relevant time, if required) and which shall be prepared in good faith and with due care and attention having undertaken such draft payroll runs as may be required (as applicable). The Purchaser shall have the right to review the Completion Allocation Schedule and the FME Shareholders' Representative shall provide reasonable access to supporting evidence and information as may reasonably be required by the Purchaser to enable the Purchaser to verify the accuracy of the Completion Allocation Schedule. The FME Shareholders' Representative and the Purchaser shall use all reasonable endeavours to reach agreement on the Proposed Completion Allocation Schedule, but to the extent that no agreement can be reached on any particular aspect, then, in respect of that matter only, the position as set out in the Completion Allocation Schedule delivered by the FME Shareholders Representative shall be deemed to be agreed for the purpose of proceedings to Completion.

[***]

- 4.6 [***]
- 4.7 [***]
- 4.8 [***]
- 4.9 [***]
- 4.10 [***]
- 4.11 [***]
- 4.12 [***]
- [***]
- 4.13 [***]
- 4.14 [***]

Subscription monies and Option Tax Liability

4.15 Each FME Shareholder:

- (a) irrevocably agrees and confirms that they will have delivered to the Company (or, for the purpose of the Share Purchase Options, to [***]) a duly completed notice of exercise immediately prior to but conditional upon Completion agreeing to sell the Shares that they will acquire on the exercise of their Options (other than a New Award in the form of an RSU Award) pursuant to this Agreement;
- (b) acknowledges and affirms that any Options (or part thereof) that they hold (other than a New Award in the form of an RSU Award) and which are not exercised prior to Completion, shall not be exercised and shall lapse immediately on Completion; and
- (c) severally and irrevocably authorises, directs and instructs [***] to deduct from their FME Shareholders' Upfront Cash Consideration an amount equal to:
 - (i) the Option Exercise Monies or, in the case of an RSU Award, any subscription price payable upon the vesting of the RSU Award; and
 - (ii) if applicable, the Estimated Tax Withholding,
 and to pay those sums (i) to the Company (such sums to be applied in accordance with the provisions of clause 4.16) in respect of all Options other than the Share Purchase Options and (ii) to [***] in respect of the Share Purchase Options.

6 Each FME Shareholder directs, and the Purchaser will procure, that the Company:

- (a) accepts, in settlement of any obligation of the FME Shareholder to pay such sums to the Company, any amount paid to it in accordance with clause 4.154c(i); and
- (b) as soon as reasonably practicable after Completion (and, in any event, within [***] days), withholds from the Estimated Tax Withholding paid to it in accordance with clause 4.15 4c(ii) in respect of that FME Shareholder an amount equal to the Option Tax Liability payable by that FME Shareholder and then pays the balance of the Estimated Tax Withholding (if any) to the FME Shareholder.

5. Consideration adjustment

5.1 After Completion the parties shall use their respective best endeavours to procure the preparation of the Completion Accounts in accordance with Schedule 9 (*Completion Accounts*).

5.2 If, following agreement or determination of the Completion Accounts in accordance with Schedule 9 (*Completion Accounts*):

- (a) the Estimated Adjustment Amount exceeds the Actual Adjustment Amount then, subject to sub-clause 5.3, the amount by which the Estimated Adjustment Amount exceeds the Actual Adjustment Amount shall be treated as a reduction from the Consideration (the "**Consideration Reduction**") and:
 - (i) if the Holdback Amount is less than the Consideration Reduction,
 - (A) the Purchaser and the Sellers irrevocably agree that the Holdback Amount is payable, and shall be paid to, the Purchaser; and
 - (B) the Sellers shall pay to the Purchaser the amount then outstanding following the release to the Purchaser of the Holdback Amount at sub-clause 5.2(a)(i)(A) in cash within [***] Business Days of the Determination Date and if no such payment is made by the FME

Shareholders, then the Purchaser and the Sellers agree that the outstanding amount due by the FME Shareholders shall be released to the Purchaser from the [***] in settlement of the FME Shareholders obligation to pay pursuant to this clause; or

- (ii) if the Holdback Amount is more than the Consideration Reduction:
 - (A) an amount equal to the Consideration Reduction is to be deducted from the Holdback Amount and the parties irrevocably agree that such amount is payable, and shall be paid to, the Purchaser; and
 - (B) the balance of the amount then outstanding following the payment at sub-clause 5.2(a)(ii)(A) is payable to the Sellers from the Holdback Amount in cash within [***] Business Days of the Determination Date,
in each case in accordance with clause 23 (*Payments*), and such set-off payment shall be apportioned between the Sellers as set out in the Completion Allocation Schedule; or
- (b) the Estimated Adjustment Amount is equal to the Actual Adjustment Amount, then there will be no adjustment to the Consideration and the Holdback Amount shall be payable to the Sellers within [***] Business Days of the Determination Date in accordance with clause 23 (*Payments*) and such payment(s) shall be apportioned between the Sellers as set out in the Completion Allocation Schedule; or
- (c) the Estimated Adjustment Amount is less than the Actual Adjustment Amount then, subject to sub-clause 5.3, the Consideration shall be treated as increased by the amount by which the Estimated Adjustment Amount is less than the Actual Adjustment Amount (the "**Consideration Increase**"). The Holdback Amount plus any additional Consideration required to satisfy the Consideration Increase shall be paid by the Purchaser to the Sellers in cash within [***] Business Days of the Determination Date. Such additional Consideration shall be apportioned between the Sellers as set out in the Completion Allocation Schedule.

5.3 If the:

- (a) Consideration Reduction is £[***] or less, then, for the purposes of sub-clause 5.2(a), the Consideration Reduction shall be deemed to be [***]. If the Consideration Reduction is more than £[***] then for the purposes of sub-clause 5.2(a) the Consideration Reduction shall be the whole of the Consideration Reduction and not just the amount that exceeds £[***]; and
- (b) If the Consideration Increase is £[***] or less, then, for the purposes of sub-clause 5.2(c), the Consideration Increase shall be deemed to be [***]. If the Consideration Increase is more than £[***] then, for the purposes of sub-clause 5.2(c) the Consideration Increase shall be the whole of the Consideration Increase and not just the amount that exceeds £[***].

5.4 Save where the contrary is expressly stated, the agreement or determination of the Completion Accounts does not constitute or operate as a waiver of any other rights, powers or remedies of the Purchaser or of any other provision of this Agreement and does not preclude the exercise of any other right, power or remedy of the Purchaser arising under this Agreement or otherwise.

6. Pre-Completion obligations

- 6.1 In so far as it is in its power to do so as a shareholder of the Company, each Seller shall, between the date of this Agreement and Completion, comply with its obligations in Schedule 8 (*Pre Completion obligations*).
- 6.2 In so far as it is in their power to do so as shareholders and/or directors (as applicable) of the Company, each Seller further undertakes, between the date of this Agreement and Completion:
 - (a) upon the written request of the Purchaser, to provide (or procure that a Group Company provides) to the Purchaser such information concerning the Business as the Purchaser may reasonably require from time to time (including for the purposes of the W&I Policy); and
 - (b) to inform the Purchaser promptly in writing if it becomes aware of any new matter or circumstance arising after the date of this Agreement which constitutes or is reasonably likely to constitute a breach of any of the Warranties or the covenants set out in sub-clause 3.6 (*Sale and purchase*).

- 6.3 No later than [***] Business Days prior to Completion, FME Shareholders Representative will deliver to the Purchaser and the Institutional Sellers a written notice ("**Estimates Notice**") setting out the amount of each of:
- (a) the Estimated Cash;
 - (b) the Estimated Debt;
 - (c) the Estimated Working Capital; and
 - (d) the Estimated Adjustment Amount,
- prepared on the basis set out in paragraph 1 of Part 2 of Schedule 9 (*Completion Accounts*) as well as a first draft of the Completion Allocation Schedule based on those estimates.
- 6.4 The FME Shareholders' Representative and the Purchaser shall engage in good faith to address any questions or comments (including the provision of documents to the Purchaser) that the Purchaser may have in connection therewith. If the Purchaser disagrees with any estimate contained within that draft Estimates Notice or anything in the draft Completion Allocation Schedule it may notify the FME Shareholders' Representatives in writing of such disagreement, in which case the Purchaser and the FME Shareholders' Representative shall attempt in good faith to resolve those matters in dispute. To the extent that no agreement can be reached on any particular aspect, then, in respect of that matter only, the position as set out in the Estimates Notice delivered by the FME Shareholders Representative (as may be updated in accordance with clause 4.5 as part of the Completion Allocation Schedule, based on the latest information available) shall be deemed to be agreed for the purpose of proceedings to Completion.
- 6.5 The Institutional Sellers Representative and the Institutional Sellers shall also engage in good faith to address any questions or comments (including the provision of documents to the Institutional Sellers) that the Institutional Sellers may have in connection therewith.
- 6.6 Each Founder Seller undertakes to procure (so far as is it is in their power to do so in accordance with Applicable Law) that (save with the prior written consent of the Purchaser) each employee of the Group shall, save in respect of employees of InstaDeep SAS, by no later than [***], use all accrued holiday entitlement in respect of the period prior to the date of this Agreement. In the event that any accrued holiday entitlement is not used by a relevant employee in accordance with this clause 6.3, the Founder Sellers shall procure that such employee's outstanding holiday entitlement in respect of the period prior to the date of this Agreement shall, so far as is permitted by Applicable Law, lapse.
- 6.7 Each Founder Seller shall, between the date of this Agreement and Completion, procure that each Minority Share Transfer is completed in accordance with all Applicable Law.
- 6.8 Each party to the Paying Agent Agreements undertakes to enter into the Paying Agent Agreements as soon as reasonably practicable following the date of this Agreement (and in any event, at least than [***] Business Days prior to Completion) and otherwise to take any actions necessary thereunder to duly appoint [***] for the purposes of this Agreement.
- 6.9 The Founder Sellers shall, subject to and to the extent permissible by Applicable Laws, and subject to reasonable advance notice being provided by the Purchaser to the Founder Sellers and/or the Company, permit the Purchaser and/or its professional advisors a right of access to the Company's premises and to inspect any Company documentation (other than any competition sensitive information in respect of the Group and the Group's business activities).
- 7. Completion**
- 7.1 Completion shall take place:
- (a) on the [***] calendar day (or, if not a Business Day, on the nearest Business Day prior to such [***] calendar day) of the [***] during which notification of the satisfaction or waiver of the Conditions in accordance with sub-clause 2.3 or sub-clause 2.10 (*Conditions precedent*) (as applicable) is received; or
 - (b) if notification of the satisfaction or waiver of the Conditions in accordance with sub-clause 2.3 or sub-clause 2.10 (*Conditions precedent*) (as applicable) occurs within the period of [***] Business Days before the [***], on the [***] of the [***] (or, if not a Business Day, on the nearest Business Day prior to such last calendar day),
- (or on such other date, time and place as the Purchaser, the Institutional Sellers and the Sellers' Representatives (excluding the Institutional Sellers' Representative) may agree, but, in any event, no later than the [***] of the date of this Agreement).
- 7.2 At Completion, the Sellers shall comply with their relevant obligations under Schedule 7 (*Completion obligations*), provided that the Sellers shall not be required to release to the Purchaser the signed stock transfer forms contemplated by paragraph 1.1(a) of Schedule 7

(*Completion obligations*) nor the Companies House webfiling authentication code until the Purchaser has complied with its obligations under sub-clause 7.3. The signed stock transfer forms and authentication code will be held in escrow by the Sellers' Solicitors until such time as the Purchaser has satisfied its obligations under sub-clause 7.3, and the same shall be released immediately without any further authority, on satisfaction of that sub-clause. The Purchaser shall not be required to deliver Consideration Shares or Consideration ADSs to any Non-US FME Shareholder unless such Non-US FME Shareholder has satisfied the relevant completion obligations under Schedule 7.

7.3 When the Sellers have complied with the provisions of sub-clause 7.2 (*Completion*), the Purchaser shall, in addition to complying with its relevant obligations under Schedule 7:

- (a) provide the Warrantors with a copy of the W&I Policy Excerpt and evidence satisfactory to the Warrantors that the W&I Policy has been put on risk;
- (b) deliver to [***] a duly signed counterpart of the Payment Notice in respect of the Initial Disbursement Amount (as each term is defined in the Paying Agent Agreement for paying agency services);
- (c) pay in accordance with clause 23 (*Payments*):
 - (i) the Estimated Sellers' Upfront Payment to the Investor Sellers for each Investor Completion Share held by them;
 - (ii) the Investor Sellers' Upfront Contingent Cash Consideration to the Investor Sellers for each Completion Share held by them;
 - (iii) the FME Shareholders' Upfront Cash Completion Payment to the Non-US FME Shareholders in respect of the Completion Shares being sold by them;
 - (iv) the US FME Shareholders Upfront Cash Completion Payment to the US FME Shareholders in respect of the Completion Shares being sold by them; and
 - (v) the Holdback Amount,

provided that [***] shall, in accordance with the Paying Agent Agreements, hold in escrow an amount equal to the Investors Holdback Amount in respect of the Investors Sellers' Shares and the FME Holdback Amount in respect of the FME Completion Shares until such time as they are due to be released in accordance with clause 5.2;

- (d) allot such total number of Consideration Shares as is set out in the Completion Allocation Schedule and which shall be calculated by:
 - (i) **deducting** from the Estimated FME Shareholders' Upfront Consideration multiplied by the number of FME Completion Shares held by the FME Shareholders the FME Shareholders' Upfront Cash Completion Payment multiplied by the same number of FME Completion Shares; and
 - (ii) **dividing** the sum resulting from (i) above **by** the Consideration ADS Price to the Depositary; and
- (e) give unconditional and irrevocable instructions to the Depositary to, and procure that the Depositary shall:
 - (i) open depositary accounts for each individual Non-US FME Shareholder; and
 - (ii) deliver such number of Consideration ADSs as is set out in the Completion Allocation Schedule against each FME Shareholder's name to the Non-US FME Shareholders on these depositary accounts with the intention that it shall be no later than 5 Business Days after the Completion Date.

7.4 If:

- (a) any of the requirements (or, for the purposes of the right to terminate as set out in sub-clause 7.4(d)(iii), any of the material requirements) of sub-clauses 7.2 or 7.3 (*Completion*) (excluding the delivery of the Consideration ADSs by the Depositary pursuant to sub-clause 7.3(e)(ii), which, the FME Shareholders acknowledge, shall not be within the control of the Purchaser, provided that the Purchaser has given the Depositary all relevant instructions and otherwise has done all that is within its control to do in order to procure delivery of the Consideration ADSs by the Depositary within the agreed timescale) are not complied with on the date set for Completion under sub-clause 7.1 (*Completion*); or
- (b) any event occurs which would constitute (i) a breach of any of the Warranties when repeated at Completion; or (ii) a right to claim under the Tax Covenant following Completion, and such event would, if the Purchaser was to acquire the Completion

Shares in accordance with this Agreement, give rise to a liability of the Sellers towards the Purchaser under this Agreement in excess of £[***]; or

- (c) there has been a material breach by the Sellers of this Agreement in the period between the date of this Agreement and Completion and, if the Purchaser was to acquire the Completion Shares in accordance with this Agreement, such material breach would give rise to a liability of the Sellers towards the Purchaser under this Agreement in excess of £[***]; or
- (d) there has been a Material Adverse Change during the period between the date of this Agreement and Completion, then the party not in breach may:
 - (i) defer Completion (including, at that party's option, with respect to some Completion Shares only, provided that such Shares are held by the party (parties) in breach) to a date [***] days after that date (in which case the provisions of this sub-clause shall also apply to Completion as so deferred); or
 - (ii) proceed to Completion so far as practicable (including, at that party's option, completion of the purchase of some Completion Shares only, provided that such Completion Shares must include all Completion Shares held by the party (parties) not in breach) but without prejudice to any other rights which it may have under this Agreement and without waiving any right to sue for breach of this Agreement or the Warranties or claim under the Tax Covenant; or
 - (iii) terminate this Agreement (other than the Surviving Provisions and the provisions of this sub-clause 7.4(iii) (*Completion*)) by notice in writing, in which event:
 - (A) the Surviving Provisions and the provisions of this sub-clause 7.4(iii) (*Completion*) shall continue to apply;
 - (B) no party shall have any claim under this Agreement of any nature whatsoever against any other party except in respect of any rights, liabilities and obligations which have accrued before termination or which accrue under any of the Surviving Provisions or under this sub-clause 7.4(iii) (*Completion*); and
 - (C) except as referred to in this sub-clause 7.4(iii) (*Completion*), all rights, liabilities and obligations of the parties under this Agreement shall cease with immediate effect.

7.5 Each Seller undertakes to promptly notify the Purchaser in writing of any breach, matter, event, condition, circumstance, fact or omission of which they become aware that may give rise to a right of termination under sub-clause 7.4 (*Completion*) save that a separate notification is not required under this sub-clause 7.5 (*Completion*) where a disclosure has been made by a Seller or any Warrantor to the Purchaser pursuant to sub-clause 6.2 (*Pre Completion obligations*).

7.6 Subject to and with effect from Completion, each party and InstaDeep acknowledges and agrees that:

- (a) each of the Shareholder Documents shall terminate and cease to have effect;
- (b) each of them shall with effect from such termination stand released and discharged from all obligations (past, present and future) arising under or resulting from the Shareholder Documents; and
- (c) none of them shall be entitled to exercise any rights or make any claims against any of the others under or in relation to the Shareholder Documents or their respective termination.

8. Post Completion matters

8.1 Each Seller irrevocably undertakes to the Purchaser that, for as long as they remain the registered holders of the Shares after Completion, they shall:

- (a) hold the Shares and any dividends and other moneys or assets paid or distributed in respect of them and all rights arising out of or in connection with them from Completion in trust for the Purchaser; and
- (b) deal with the Shares and all such dividends, distributions and rights as the Purchaser may direct from Completion until the date on which the Purchaser or its nominee is entered in the register of members of the Company as the holder of the Shares.

- 8.2 Each Seller irrevocably (by way of security to secure the proprietary interest of the Purchaser as purchaser of the Completion Shares) and unconditionally appoints the Purchaser as its attorney to do and perform any acts and things which the Purchaser in its absolute discretion considers necessary or desirable in connection with the Completion Shares from Completion until the date on which the Purchaser or its nominee is entered in the register of members of the Company as the holder of the Completion Shares, including (without prejudice to the generality of the foregoing):
- (a) exercising any rights, privileges or duties attaching to the Completion Shares including, without limitation, receiving notices of, and attending and voting at, all meetings of the shareholders of the Company and meetings of the members of any particular class of the Completion Shares and all or any adjournment of such meetings; and
 - (b) completing and delivering any consents, proxies or resolution and any other documents required to be signed by a Seller as a member of the Company from Completion until the date on which the Purchaser or its nominee is entered in the register of members of the Company as the holder of the Completion Shares.
- 8.3 For the purpose of sub-clause 8.2 (*Post Completion matters*), each Seller irrevocably and unconditionally authorises the Company from Completion to send any notices in respect of its shareholding to the Purchaser and the Company shall not be required also to send such notices to the relevant Seller.
- 8.4 The Purchaser undertakes to:
- (a) without unreasonable delay, and in any event no later than [***] Business Days following the date of Completion, apply to HM Revenue & Customs for stamping on the transfer of the Completion Shares it has acquired;
 - (b) notify the Company without delay after confirmation of stamping of the transfer of the Completion Shares it has acquired is received (and in any event no later than [***] Business Days thereafter), by providing a copy of the relevant confirmation received from HM Revenue & Customs; and
 - (c) procure that the Company updates its register of members without delay and in any event no later than [***] Business days after being presented by the Purchaser with a copy of the relevant confirmation received from HM Revenue & Customs.
- 9. Purchaser's Employee Incentive Plan**
- 9.1 The Purchaser shall:
- (a) within [***] following Completion, approve and adopt the Purchaser's Employee Incentive Plan by resolution of its management board and supervisory board; and
 - (b) as soon as practicable following Completion, procure the submission of the application to the Central Bank of Tunisia and South African Reserve Bank (as applicable) in respect of the EIP Conditions.
- 9.2 The implementation, payment and awards issued (as appropriate) by the Purchaser pursuant to the Purchaser's Employee Incentive Plan shall, at all times, be subject to, and made in accordance with, the Purchaser's Employee Incentive Plan.
- 10. Warranties**
- 10.1 The Warrantors severally warrant to the Purchaser in the terms of the Warranties, save as Disclosed, as at the date of this Agreement and again as at the Completion Date, by reference to the facts and circumstances existing at that time.
- 10.2 Each of the Warranties is a separate and independent Warranty and shall not be limited by reference to any other Warranty or anything in this Agreement (save to the extent expressly provided to the contrary in Schedule 5 (*Limitations on liability*) or paragraph 3 of the Tax Schedule).
- 10.3 Unless the context otherwise requires, each of the Warranties given by or relating to the Company shall be deemed to be given by or relate to all Group Companies (or each or any of them as the context requires) and any reference to the Company in a Warranty shall be deemed to be a reference to all Group Companies (or each or any of them as the context requires).
- 11. Tax Covenant**
- The Warrantors covenant to the Purchaser in the terms of the Tax Covenant.

12. [***]

13. Purchaser's remedies

13.1 The rights and remedies of the Purchaser in respect of any breach of the Warranties, the [***] or the Tax Covenant or any other provision of this Agreement shall not be affected by Completion.

13.2 If any Claim [***] under any other provision of this Agreement is made, save in the event of fraud, no Seller shall make any claim against any Group Company or any director or employee of any Group Company (each a "**Relevant Person**") on whom it may have relied before agreeing to any provisions of this Agreement or authorising any statement in the Signing Disclosure Letter and/or the Completion Disclosure Letter.

13.3 Any amount paid by the Sellers to the Purchaser in respect of any of the provisions of this Agreement shall be treated as paid to the Purchaser by way of pro rata reduction in the Consideration (as such may be adjusted pursuant to clause 5 (*Purchase price adjustment*)).

13.4 Subject to clause 13.5, if in respect of or in connection with any Warranty Claim, any amount payable to the Purchaser by the Warrantors is subject to Taxation, the amount to be paid to the Purchaser by the Warrantors shall be such as to ensure that the net amount retained by the Purchaser after such Taxation has been taken into account is equal to the full amount which would be payable to the Purchaser had the amount not been subject to Taxation.

13.5 The provisions of clause 13.4 shall not apply if and to the extent that:

- (a) the amount payable in respect of or in connection with the Warranty Claim has included an amount for, or otherwise taken into account, such Taxation;
- (b) the Purchaser (including any other recipient of the payment) is at any time resident for Tax purposes in a jurisdiction other than Germany and the amount payable (if any) pursuant to or in consequence of clause 13.4 would have been less had the Purchaser (or other recipient) been at all times so resident only in Germany.

14. Limitations on liability

14.1 The liability of the Warrantors in respect of any Claim shall be limited as provided in Schedule 5 (*Limitations on liability*) but provided always that notwithstanding any other provision in this Agreement, the provisions of this clause 14 (*Limitations on liability*) and Schedule 5 (*Limitations on liability*) and Part 4 of the Tax Schedule shall not apply to any Claim made against the Warrantors to the extent that the Claim (or the delay in the discovery of it) is the consequence of or is increased as a consequence of any fraud or dishonesty or any wilful misstatement, concealment or omission on the part of any of the Warrantors or their advisers.

14.2 The total aggregate liability of a Seller to the Purchaser in respect of any and all claims under this Agreement (including any liability for interest, Tax and legal, professional and other costs and expenses incurred by the Purchaser or a Group Company in relation to such claim) shall not exceed the amount of Consideration actually received by that Seller (calculated on the same basis as such Consideration is paid to the relevant Seller). The liability of a Seller to the Purchaser in connection with any claim for breach of sub-clauses 3.6 and 3.7 of this Agreement shall be limited to [***], save in the event of fraud or dishonesty or wilful misconduct on the part of the relevant Seller.

14.3 Except as otherwise provided in respect of Claims under Schedule 5 (*Limitations on liability*), no Seller shall be liable for any claim under this Agreement unless the Purchaser has served written notice to the Sellers' Representatives, containing a reasonable details of the nature of the claim as far as it is known to the Purchaser, on or prior to the expiration of:

- (a) [***] from the expiry of the Restricted Period in respect of a claim under clause 17 (*Protection of goodwill*); or
- (b) [***] from Completion in respect of all other claims.

14.4 Except as otherwise expressly provided in this Agreement, no Seller shall be liable in respect of all or any portion of a claim under this Agreement to the extent that the matter giving rise to it results from:

- (a) any act done or omitted to be done at the written request of or with the written approval of the Purchaser or another member of the Purchaser's Group; or
- (b) any act done or omitted to be done on or after Completion by or on behalf of the Purchaser or any member of the Purchaser's Group or the Purchaser's successors in title to the Completion Shares;
- (c) any breach by the Purchaser of its obligations under this Agreement or any other document entered into in connection with it; or

- (d) any change after Completion in the accounting policies or practices used in preparing any Group Company's accounts or in the accounting reference date of any Group Company, save for any changes required to comply with generally accepted accounting practice.
- 14.5 Paragraphs 3(b)(i), 7(c), 7(d), 9, 11 to 13 (inclusive) of Schedule 5 (Limitations *on liability*) shall apply to also limit the liability of each Seller, *mutatis mutandis*.
- 15. Purchaser's conduct of Third Party Claims**
- 15.1 The Purchaser shall notify the Warrantors in writing of:
- (a) any claim made against it by a third party which may give rise to a Non-Tax Claim; and
 - (b) any claim any Group Company is entitled to bring against a third party which claim is based on circumstances which may give rise to a Non-Tax Claim,
- each such claim being a "**Third Party Claim**".
- 15.2 The Purchaser shall procure that the conduct, negotiation, settlement or litigation of such Third Party Claim is, so far as is reasonably practicable, carried out in accordance with the wishes of the Warrantors and/or the W&I Insurer and at their cost subject to their giving timely instructions to the Purchaser and providing reasonable security for any costs and expenses which might be incurred by the Purchaser or any Group Company and provided that:
- (a) nothing in this clause 15 shall oblige the Purchaser to take any action which it considers to be detrimental to the business, trading relationships or reputation of any Group; and
 - (b) the provisions of this clause 15 shall not apply in relation to the relevant Third Party Claim if they could render any policy of insurance (including the W&I Policy) maintained by or available to the Purchaser or any other member of the Purchaser's Group void or voidable, or entitle the relevant insurer (including any W&I Insurer) to repudiate or rescind any such policy in whole or in part, or in the event that a relevant insurer (including any W&I Insurer) exercises its right to take over conduct of such Third Party Claim.
- 15.3 The rights of the Warrantors under this clause 15 (*Purchaser's conduct of Third Party Claims*) shall only apply to such Third Party Claim if the Warrantors jointly give notice to the Purchaser in writing of their intention to exercise their rights within [***] Business Days of the Purchaser giving notice of such Third Party Claim. If the Warrantors do not give notice during that period the Purchaser shall be entitled in its absolute discretion to settle, compromise, or take or resist any action, proceedings or claim in respect of such Third Party Claim. Until such time as the time period expires or the Warrantors do give notice of their intention to take conduct of the Third Party Claim, the Purchaser shall, or as the case may be shall procure that the Company shall:
- (a) consult with the Warrantors as soon as reasonably practicable with regard to the Third Party Claim in question;
 - (b) provide the Warrantors on request with copies of all documents in relation to the relevant Third Party Claim, save where to do so would result in a breach of any obligation of confidentiality or the loss of legal professional privilege;
 - (c) take reasonable account of the views of the Warrantors with regard to the Third Party Claim in question; and
 - (d) not admit liability in respect of or settle or compromise the relevant Third Party Claim without the prior written consent of the Warrantors, such consent not to be unreasonably withheld or delayed.
- 15.4 The Purchaser shall provide and shall procure that the Company provides to the W&I Insurer, the Warrantors and the W&I Insurer's professional advisers reasonable access to premises and personnel and to any relevant assets, documents and records within their power, possession or control for the purpose of investigating any Non-Tax Claim and/or enabling the Warrantors and/or the W&I Insurer to take the action referred to in sub-clause 15.2 and shall allow the Warrantors and/or the W&I Insurer and their professional advisers to take copies of any relevant documents or records at their expense.
- 15.5 Subject to the prior entering into of reasonable confidentiality obligations by the Warrantors and their professional advisers, the Purchaser shall provide and shall procure that the Group provides to the Warrantors and their professional advisers reasonable access to premises and personnel and to any relevant assets, documents and records within their power, possession or control for the purpose of investigating any Third Party Claim and enabling the Warrantors to take the action referred to in sub-clause 15.2 (*Purchaser's conduct of Third Party Claims*)

and shall allow the Warrantors and their professional advisers to take copies of any relevant documents or records at its sole expense.

16. The W&I Policy

- 16.1 The Purchaser shall not, without the prior written consent of the Warrantors, agree to any material amendment, variation or waiver of the W&I Policy with the W&I Insurer, the effect of which would, or could reasonably be expected to, increase the liability of the Warrantors in respect of a Claim.
- 16.2 The Warrantors acknowledge and agree with the Purchaser that the Warrantors shall not have any interest in the W&I Policy and shall not have any right or entitlement to receive any payment made by the W&I Insurer under the W&I Policy or to receive any payment, benefit or relief which is derived from or which is otherwise attributable to any payment under the W&I Policy.

17. Protection of goodwill

- 17.1 In order to assure to the Purchaser the full benefit of the business and goodwill of the Group, each Restricted Person severally undertakes on his/her own behalf that (save as may be bona fide in fulfilling his/her duties as an employee of any Group Company thereafter) they shall not directly or indirectly (whether as principal, shareholder, partner, employee, agent or otherwise), whether on its own account or in conjunction with or on behalf of any other person, do any of the following things:
- (a) during the Restricted Period carry on or be engaged, concerned or interested in (except as the holder of shares in a company whose shares are listed on a recognised investment exchange or overseas investment exchange (as such terms are defined in Sections 285 and 313, Financial Services and Markets Act 2000) which confer not more than [***]% of the votes which could normally be cast at a general meeting of that company) any business which competes with any part of the Restricted Business; or
 - (b) during the Restricted Period canvass or solicit or seek to entice away the custom of any Client or Prospective Client for the purposes of providing Restricted Business; or
 - (c) during the Restricted Period employ or otherwise engage any Key Employee; or
 - (d) during the Restricted Period endeavour to entice away from any Group Company or encourage to terminate his employment with any Group Company (whether or not such termination would be a breach of his contract of employment) any person who is or was a Senior Employee during the [***] period prior to Completion; or
 - (e) save as required by law, during the Restricted Period do or say anything likely or calculated to lead any person to withdraw from or cease to continue offering to any Group Company any rights (whether of purchase, sale, import, distribution, agency or otherwise) then enjoyed by it or in any other way to cease to do business or reduce the amount of business it transacts with any Group Company; or
 - (f) save in the circumstances referred to in sub-clause 19.10(b) (*Confidentiality*), disclose to any other person any information which is secret or confidential to the business or affairs of the Group or any Purchaser Group Company or use any such information to the detriment of the business of the Group or any Purchaser Group Company for so long as that information remains secret or confidential; or
 - (g) in relation to a business which is competitive or likely to be competitive with the Restricted Business, use any trade or business name or distinctive mark, style or logo used by or in the business of any Group Company at Completion or anything intended or likely to be confused with it.
- 17.2 Each undertaking contained in this clause 17 (*Protection of goodwill*) shall be construed as a separate and independent undertaking and, while the restrictions set out in this clause are considered by the parties to be reasonable in all the circumstances, it is agreed that if any one or more of such restrictions shall, either taken by itself or themselves together, be adjudged to go beyond what is reasonable in all the circumstances for the protection of the Purchaser's legitimate interests but would be adjudged reasonable if any particular restriction or restrictions were deleted or any part or parts of the wording thereof were deleted, restricted or limited in any particular manner (including without limitation any reduction in their duration or geographical scope) then the said restrictions shall apply with such deletions, restrictions or limitation as the case may be.
- 17.3 Each of the Founder Sellers severally agrees that, having regard to the facts and matters set out above and having taken professional advice, the restrictions contained in this clause 17 (*Protection of goodwill*) are reasonable and necessary for the protection of the legitimate business interests of the Purchaser.

18. Consideration Shares

- 18.1 Subject to the remainder of this clause 18, each of the Non-US FME Shareholders severally covenants with and undertakes to the Purchaser that they will not make any Disposal during the period commencing on the date of Completion and ending on the [***] of the Completion Date (the "Lock-up Period").
- 18.2 The number of Consideration Shares or Consideration ADSs that are the subject of the restriction in sub-clause 18.1 shall be reduced and shall cease to be subject to the restriction in sub-clause 18.1 as follows:
- (a) on the date that is [***] after the Completion Date, [***]% of the Consideration ADSs issued to each Non-US FME Shareholder and the Consideration Shares represented thereby;
 - (b) in addition to the number of Consideration ADSs and the Consideration Shares represented thereby released pursuant to sub-clause 18.2(a), on the [***] of the Completion Date, [***]% of the Consideration ADSs issued to each Non-US FME Shareholder; and
 - (c) in addition to the number of Consideration ADSs and the Consideration Shares represented thereby released pursuant to sub-clause 18.2(a) and 18.2(b), on the [***] of the Completion Date, the balance of the Consideration ADSs issued to each Non-US FME Shareholder and the Consideration Shares represented thereby,
- such release schedule in respect of each Non-US FME Shareholder being set out opposite his or her name in the Completion Allocation Schedule.
- 18.3 Each Non-US FME Shareholder and the Purchaser hereby acknowledges and agrees that the Consideration Shares and Consideration ADSs:
- (a) are being issued and sold outside the United States in reliance on Regulation S;
 - (b) have not been and will not be registered under the Securities Act or any other securities laws;
 - (c) may not be offered or sold within the United States (as defined in Regulation S) except pursuant to an available exemption from the registration requirements of the Securities Act; and
 - (d) may bear the following or a similar restrictive legend:
"These shares have not been registered under the Securities Act of 1933 ("the Act"). These shares may not be offered for sale, sold, transferred, assigned, pledged or hypothecated except (i) pursuant to an effective registration statement under the Act, or (ii) pursuant to an available exemption from registration under the Act."
- 18.4 The Purchaser warrants to the Non-US FME Shareholders both at the date of this Agreement and again at Completion that:
- (a) none of the Purchaser, any Purchaser Group Company or any person acting on its or their behalf has, directly or indirectly, made offers or sales of, or has solicited offers to buy, or otherwise has negotiated in respect of, any security under circumstances that would require the Consideration Shares or the Consideration ADSs to be registered under the Securities Act;
 - (b) none of the Purchaser, any Purchaser Group Company or any person acting on its or their behalf has engaged in any directed selling efforts (as defined in Regulation S) with respect to the Consideration Shares and the Consideration ADSs, and it and they have complied and will comply with the offering restrictions of Regulation S;
 - (c) the Purchaser is a "foreign issuer" (as such term is defined in Regulation S) and there is no "substantial US market interest" (as such term is defined in Regulation S) in the Consideration Shares or the Consideration ADSs or any securities of the same class as the Consideration Shares or the Consideration ADSs; and
 - (d) none of the Purchaser, any Purchaser Group Company or any person acting on its or their behalf, directly or indirectly, has entered into any contractual arrangement with a distributor (as defined in Regulation S) with respect to the Consideration Shares or the Consideration ADSs.
- 18.5 The Purchaser irrevocably undertakes to and covenants with each of the Non-US FME Shareholders that it will, following the expiration of any applicable 40 day compliance period (as such term is used in Regulation S) in respect of any issuance of Consideration Shares or Consideration ADSs, take all necessary steps for the removal of the restrictive legend provided under sub-clause 18.3(d) from the face of the applicable Consideration Shares or

Consideration ADSs, including if required by the Depositary, obtaining an opinion of counsel in respect of the applicable Consideration Shares or Consideration ADSs.

19. General

19.1 Entire agreement

- (a) This Agreement and all of the documents in the agreed form sets out the entire agreement and understanding between the parties and supersedes all prior agreements, understandings or arrangements (whether oral or written) in respect of the subject matter of this Agreement.
- (b) Each party acknowledges that it has entered into this Agreement in reliance only upon the warranties, promises and terms specifically contained or expressly referred to in this Agreement and, save as expressly set out in this Agreement, no party shall have any liability in respect of any other warranty or promise made prior to the date of this Agreement, unless it was made fraudulently.

19.2 Contracts (Rights of Third Parties) Act 1999

- (a) Save as expressly provided in sub-clause 19.2(b), no term of this Agreement (whether express or implied) is enforceable pursuant to the Contracts (Rights of Third Parties) Act 1999 or otherwise by any person who is not a party to it. For the avoidance of doubt, the terms of this Agreement may be enforced by each New FME Shareholder duly executing and delivering a Deed of Adherence.
- (b) Subject to sub-clause 19.4(b) (*Variation*):
 - (i) the Company may enforce sub-clause 8.3 (*Post completion matters*);
 - (ii) each Group Company may enforce clause 3 (*Sale and Purchase*); and
 - (iii) each Relevant Person (as such is defined) may enforce sub-clause 13.1 (*Purchaser's remedies*).

19.3 Assignment

- (a) This Agreement shall be binding on and enure for the benefit of the successors in title of the parties but, except as set out in sub-clause 19.3(b), shall not be assignable by any party without the prior written consent of the other.
- (b) The Purchaser may assign the benefit of this Agreement (including, without limitation, the Warranties) to:
 - (i) any Purchaser Group Company;
 - (ii) any successor in title or any subsequent purchaser of the Completion Shares; or
 - (iii) by way of security to any bank or financial institution,and, in the event of any such assignment, all references in this Agreement to the Purchaser shall be deemed to include its assigns.

19.4 Variation

- (a) Subject to sub-clause 19.4(b), no purported variation of this Agreement shall be effective unless it is in writing and signed by or on behalf of each of:
 - (i) the Purchaser;
 - (ii) only to the extent the purported variation affects any rights of the Institutional Sellers, each Institutional Seller; and
 - (iii) the Sellers' Representatives (excluding the Institutional Sellers' Representative).
- (b) Pursuant to Section 2(3)(a), Contracts (Rights of Third Parties) Act 1999, the Purchaser, the Institutional Sellers and the Sellers' Representatives, in accordance with sub-clause 19.4(a), may without limit or restriction vary this Agreement or any provision of it which may be enforced by a third party or otherwise amend this Agreement in such a way as to extinguish or alter such third party's entitlement under any such provision without the consent of that third party.

19.5 Effect of Completion

Except to the extent already performed, all the provisions of this Agreement shall, so far as they are capable of being performed or observed, continue in full force and effect notwithstanding Completion.

19.6 Invalidity

To the extent that any provision of this Agreement is found by any court or competent authority to be invalid, unlawful or unenforceable in any jurisdiction, that provision shall:

- (a) be deemed not to be a part of this Agreement;
- (b) not affect the enforceability of the remainder of this Agreement; and
- (c) not affect the validity, lawfulness or enforceability of that provision in any other jurisdiction.

19.7 Releases and waivers

- (a) The rights, powers and remedies conferred on any party by this Agreement and the remedies available to any party are cumulative and are additional to any right, power or remedy which it may have under general law or otherwise.
- (b) Any party may, in whole or in part, release, compound, compromise, waive or postpone, in its absolute discretion, any liability owed to it or right granted to it in this Agreement by any other party or parties without in any way prejudicing or affecting its rights in respect of that or any other liability or right not so released, compounded, compromised, waived or postponed.
- (c) No single or partial exercise, or failure or delay in exercising any right, power or remedy by any party shall constitute a waiver by that party of, or impair or preclude any further exercise of, that or any right, power or remedy arising under this Agreement or otherwise.

19.8 Further assurance

After Completion, the Sellers shall execute such documents and take such steps as the Purchaser may reasonably require to vest the full title to the Completion Shares in the Purchaser, to fulfil the provisions of this Agreement and to give the Purchaser the full benefit of this Agreement.

19.9 Counterparts

- (a) This Agreement may be executed in any number of counterparts and by the parties on separate counterparts, but shall not be effective until each party has executed at least one counterpart.
- (b) Each counterpart, when executed, shall be an original of this Agreement and all counterparts shall together constitute one instrument.

19.10 Confidentiality

- (a) Except as referred to in sub-clause 19.10(b), each party shall treat as strictly confidential all information received or obtained as a result of entering into or performing this Agreement which relates to the provisions or subject matter of this Agreement, to any other party or to the negotiations relating to this Agreement.
- (b) Any party may disclose information which would otherwise be confidential if and to the extent:
 - (i) it is required to do so by law or any securities exchange or regulatory or governmental body to which it is subject wherever situated;
 - (ii) it considers it necessary to disclose the information to its professional advisers, auditors and bankers provided that it does so on a confidential basis;
 - (iii) the information has come into the public domain through no fault of that party;
 - (iv) the information is required to be disclosed to the W&I Insurer or any broker advising on the W&I Policy in connection with the arrangement or administration of, or any claim to be made under, the W&I Policy;
 - (v) the information was previously disclosed to it without any obligation of confidence; or
 - (vi) each party to whom it relates has given its consent in writing.

19.11 Independent Expert

- (a) Where any matter in this Agreement is to be referred to the decision of an Independent Expert including pursuant to Schedule 9 (*Completion Accounts*) and clause 4.4 (*FME Shareholders' Transaction Tax Liability*), the provisions of this sub-

clause 19.11 will apply to the Independent Expert's appointment and terms of reference.

- (b) The Independent Expert shall be Deloitte, Klynveld Peat Marwick Goerdeler (KPMG), Grant Thornton or BDO as either:
 - (i) jointly agreed between the Sellers' Representatives (or, if the decision is in relation to the Earn-Out Consideration, the FME Shareholders' Representative) and the Purchaser within [***] days of the referral referred to in sub-clause 19.11(a); or
 - (ii) failing such agreement within such [***]-day period, to be nominated by either:
 - (A) the President for the time being of the Institute of Chartered Accountants in England and Wales ("**ICAEW President**") (or the next most senior officer available) upon the joint written application of the Sellers' Representatives (or, if the decision is in relation to the Earn-Out Consideration, the FME Shareholders' Representative) and the Purchaser (together with the applicable application fee (which shall be paid as to one half by the Purchaser and as to one half by the Sellers (or, if the decision is in relation to the Earn-Out Consideration, the FME Shareholders))) and required forms), or
 - (B) where the relevant Sellers' Representatives and the Purchaser fail to make a joint application to the ICAEW President within [***] days after the failure of the Sellers' Representatives and the Purchaser to agree upon the Independent Expert, the London Court of International Arbitration upon the written application of either the Sellers' Representatives (or, if the decision is in relation to the Earn-Out Consideration, the FME Shareholders' Representative) or the Purchaser (together with the applicable application fee (which shall be paid by the party making the application)).
- (c) The Purchaser and the relevant Sellers' Representatives shall use all reasonable endeavours to reach agreement regarding the identity of the person to be appointed as the Independent Expert (who shall be required to have experience in M&A transactions) and to agree terms of appointment with the Independent Expert and neither party shall unreasonably withhold its agreement to the terms of appointment proposed by the Independent Expert or the other party.
- (d) If a nominating body is called upon to nominate an Independent Expert pursuant to sub-clause 19.11(b), such nominating body shall also agree the Independent Expert's terms of appointment on behalf of the Purchaser and the relevant Sellers' Representatives.
- (e) Each of the Purchaser and the relevant Sellers' Representatives shall co-operate with the Independent Expert and promptly on request supply to the Independent Expert such documents and information as the Independent Expert may require for the purpose of the reference and in order to enable the determination to be reached as soon as reasonably practicable and in any event within any time period set by this Agreement.
- (f) The Purchaser and the relevant Sellers' Representatives shall be entitled to make submissions to the Independent Expert and each such party shall, with reasonable promptness, supply the other party with all such information and access to its documents, books and records as the other party may reasonably require in order to make a submission to the Independent Expert in accordance with this clause.
- (g) To the extent not provided for in this sub-clause 19.11, the Independent Expert may in its reasonable discretion determine such other procedures to assist with the conduct of its determination as it considers just or appropriate.
- (h) Unless otherwise agreed by the parties or as otherwise expressly provided in this Agreement, the Independent Expert shall:
 - (i) be required to make its determination in writing (including reasons for its determination) within the range proposed by each party and to provide a copy to each party as soon as reasonably practicable and in any event within [***] Business Days of its appointment (unless the Independent Expert otherwise determines);
 - (ii) be entitled to make any determination as to the interpretation of this Agreement as is necessary in the reasonable opinion of the Independent Expert to enable a determination of the matters so referred to be made; and

- (iii) be entitled to take legal advice on any matter relevant to the determination.
- (i) The Independent Expert shall act as an expert and not as an arbitrator and neither the Arbitration Act 1996 nor any earlier or later enactments on arbitration shall apply.
- (j) The Independent Expert's decision shall (in the absence of manifest error or fraud) be final and binding on the Parties for all the purposes of this Agreement. Where a manifest error results from a computational, clerical or typographical error, the relevant part of the determination shall be void and shall be referred back to the Independent Expert for correction.
- (k) The costs of the Independent Expert shall be apportioned between the parties as the Independent Expert shall decide but each party shall be responsible for its own costs of presenting its case to the Independent Expert. If the Independent Expert shall not determine how its costs shall be determined, his costs shall be borne [***] by the Seller (or, if the decision is in relation to the Earn-Out Consideration, the FME Shareholders) [***] and the Purchaser [***].
- (l) if the Independent Expert dies or becomes unwilling or incapable of acting, or does not deliver its determination within the period required by this sub-clause 19.11, the Purchaser and the Sellers' Representatives shall use all reasonable endeavours to agree the identity and terms of appointment of a replacement Independent Expert and the provisions of sub-clause 19.11(b) shall apply mutatis mutandis. This sub-clause 19.11 shall apply in relation to each and any replacement Independent Expert as if it was the first Independent Expert appointed.
- (m) The Purchaser and the Sellers' Representatives shall act reasonably and co-operate to give effect to the provisions of this sub-clause 19.11 and shall not do anything to hinder the Independent Expert or prevent it from making its determination.

19.12 **Set-off**

- (a) If, on the Earn-out Consideration Completion Date:
 - (i) a Due Amount (or any part of it) is outstanding, the Purchaser shall be entitled (at its sole discretion) to satisfy all (to the extent possible) or part of the relevant FME Shareholders' liability to pay such Due Amount by way of set-off against any Payment Amount, and to reduce the Purchaser's obligation to make any Payment Amount by the amount so set off; and/or
 - (ii) there is an Outstanding Claim, the Purchaser shall be entitled (at its sole discretion) to:
 - (A) withhold from the Payment Amount an amount equal to the Estimated Liability in respect of that Outstanding Claim or, if lower, the full amount of the Payment Amount (the "**Reserved Sum**"); and
 - (B) defer payment of the Reserved Sum until such time as the Outstanding Claim has become a Resolved Claim.
- (b) Where the provisions of sub-clause 19.12(a)(ii) apply, the Purchaser and the relevant Sellers shall use all reasonable endeavours to agree the Estimated Liability in respect of the Outstanding Claim as soon as possible, and in any event, within the period of [***] Business Days following the Earn-out Consideration Completion Date. In the absence of such agreement, the following procedure shall apply:
 - (i) the determination of the Estimated Liability shall be referred to Counsel at the request of either party and Counsel shall be jointly appointed by the affected parties;
 - (ii) Counsel shall be requested to provide their determination of the Estimated Liability within [***] Business Days of accepting their appointment (or such other period as the Purchaser and the relevant Sellers may otherwise agree with Counsel);
 - (iii) Counsel shall act as an expert and not as arbitrator and their determination regarding the amount of the Estimated Liability shall, in the absence of manifest error, be final and binding on all the parties;
 - (iv) Counsel's fees shall be borne by the Purchaser (on the one part) and the relevant Sellers (on the other part) equally or as Counsel may otherwise direct having regard to the respective conduct of the parties;
 - (v) if Counsel has not been able to determine the amount of the Estimated Liability, then the Estimated Liability shall be deemed to be the median value

of the Purchaser's and the relevant Sellers' reasonable good faith estimates of such Estimated Liability; and

- (vi) if Counsel has provided a determination of the Estimated Liability in the form of a range of figures, then the Estimated Liability shall be deemed to be the median value of such estimates.
- (c) Where a Reserved Sum has been withheld by the Purchaser pursuant to sub-clause 19.12(a)(ii) in respect of an Outstanding Claim, on that claim becoming a Resolved Claim the Purchaser shall:
- (i) be entitled (at its sole discretion) to satisfy all (to the extent the Reserved Sum is sufficient) or part of the relevant Sellers' liability to pay the Due Amount in respect of the relevant Resolved Claim by way of set-off against the corresponding Reserved Sum, and to reduce the Purchaser's obligation to make any Payment Amount by the amount so set off; and
 - (ii) pay to the relevant Sellers the remaining balance of the corresponding Reserved Sum (if any) after the Purchaser has exercised its rights pursuant to sub-clause 19.12(c)(i). Such payment shall be made by the Purchaser within [***] Business Days of the Outstanding Claim becoming a Resolved Claim.
- (d) Notwithstanding the provisions of sub-clause 19.12(c), where the amount of the Estimated Liability determined by Counsel in accordance with sub-clause 19.12(b) is less than the Reserved Sum, the Purchaser shall pay to the relevant Sellers the balance of the corresponding Reserved Sum within [***] Business Days after Counsel determines the amount of the Estimated Liability in accordance with sub-clause 19.12(b).
- (e) Nothing in this sub-clause 19.12 shall prejudice, limit or otherwise affect:
- (i) any right or remedy the Purchaser may have against the Sellers (or any of them) from time to time under this Agreement or any of the other Transaction Documents or at law; or
 - (ii) the Purchaser's right to recover against the Sellers (or any of them), whether before or after the Earn-out Consideration is paid in accordance with this Agreement.
- (f) The amount of a Reserved Sum withheld by the Purchaser in accordance with this sub-clause 19.12 shall not be regarded as imposing any limit on the amount of any claims under this Agreement or any of the other Transaction Documents or at law.
- (g) If a Due Amount is not satisfied in full by way of set-off under sub-clause 19.12(a)(i) or sub-clause 19.12(c), nothing in this Agreement shall prevent or otherwise restrict the Purchaser's right to recover the balance from the Sellers (or any of them) and the Due Amount (to the extent not so satisfied) shall remain fully enforceable against the relevant Sellers.

20. Announcements

- 20.1 Except as provided in sub-clause 20.2 (*Announcements*), no announcement, circular or other communication (whether oral or written) concerning the terms of this Agreement (or the transaction contemplated or referred to in it) shall be made or issued by or on behalf of any of the parties without the prior written consent of the Purchaser, such consent not to be unreasonably withheld or delayed.
- 20.2 Any announcement, circular or other communication made or issued by or on behalf of any party which is required by law or the rules of any regulatory or governmental body to which such party is subject, including, without limitation, any stock exchange on which any securities of such party are listed, may be made or issued by or on behalf of that party without consent if it has first sought consent and given the other parties a reasonable opportunity to comment on the subject matter and form of the announcement or circular (given the time scale within which it is required to be released or despatched).
- 20.3 The obligations in this clause 20 (*Announcements*) shall cease to apply to the Purchaser after Completion.
- 20.4 Nothing in this clause 20 (*Announcements*) shall restrict the Purchaser or any other Purchaser Group Company from:
- (a) providing information regarding the acquisition of the Company to its shareholders; or
 - (b) informing customers or suppliers of the acquisition of the Company by the Purchaser after Completion.

21. Costs and expenses

- 21.1 Except as set out in sub-clause 21.2 (*Costs and expenses*) or otherwise expressly provided in this Agreement, each party shall bear its own costs and expenses incurred in the preparation, execution and implementation of this Agreement.
- 21.2 The Purchaser shall pay all stamp and other transfer duties and registration fees applicable to any document to which it is a party and which arise as a result of or in consequence of this Agreement.

22. [***]

23. Payments

23.1 Save as expressly provided to the contrary in this Agreement:

- (a) any payment to be made pursuant to this Agreement by the Purchaser from time to time (including the Consideration) shall be made to the Sellers' Bank Account, unless otherwise agreed between the Purchaser and the relevant Seller;
- (b) any payment to be made pursuant to this Agreement by the Sellers or the Warrantors shall be made to the Purchaser's Bank Account; and
- (c) payment under sub-clauses 23.1(a) and/or (b) shall be in immediately available funds by electronic transfer on the due date for payment. Receipt of the amount due shall be an effective discharge of the relevant payment obligation, including where such amount is paid by the Purchaser to [***] in accordance with the provisions of this Agreement and the Paying Agent Agreements.

24. Notices

- 24.1 Subject to clauses 25 (*Service of Proceedings*), 26.1 (*Sellers' Representatives*) and 27.1 (*Institutional Sellers' Representative*), any notice to a party under this Agreement shall be in writing in English signed by or on behalf of the party giving it and shall, unless delivered to a party personally, be left at, or sent by prepaid recorded delivery (to addresses in the UK only) or by courier, or by email to the address of the party as set out in column B of Part 1 of Schedule 1 and column B of Part 2 of Schedule 1 (as applicable) and to [***] for the Purchaser or as otherwise notified in writing from time to time, save that delivery by email does not apply to the service of any proceedings or other documents in any legal action or proceedings or, where applicable, any arbitration or other method of dispute resolution.
- 24.2 Except as referred to in sub-clauses 24.3 (*Notices*), a notice shall be deemed to have been served at the time of delivery if delivered personally or left at an address by a courier.
- 24.3 In the case of delivery in person or by courier, if the deemed time of service is not during business hours in the country of receipt, the notice shall be deemed served at the opening of business on the next business day of that country.
- 24.4 In proving service it shall be sufficient to prove:
- (a) in the case of personal service, that it was handed to the party or delivered to or left in an appropriate place for receipt of letters at its address;
 - (b) in the case of a letter sent by recorded delivery or courier, a receipt by the courier or postal service confirming that the letter was accepted for delivery and was correctly addressed to the intended recipient in accordance with this clause; and
 - (c) in the case of email, that it was properly addressed and despatched to the email address of the party, provided that the sender of the email does not receive an automated response from the recipient or a mail server indicating that the recipient is out of office or that the email could not be delivered.
- 24.5 Any notice to be given to the Institutional Sellers (or any one of them) under clause 24.1 shall be sent to each Institutional Seller directly and, if the notice is not sent by email, shall also be sent by email to the email address of the relevant Institutional Seller as set out in column B of Part 2 of Schedule 1 (which shall not constitute notice for the purposes of this clause 24).
- 24.6 A party shall not attempt to prevent or delay the service on it of a notice connected with this Agreement.

25 Service of Proceedings

- 25.1 If, for any reason, the Purchaser requests any Seller who is located outside of England and Wales to do so, the relevant Seller shall promptly:
- (a) appoint an agent for service of process and any other documents in proceedings in England or any other proceedings in connection with this Agreement with an address in England; and

- (b) advise the Purchaser of the agent's name and address,

and if, following such a request the relevant Seller fails to appoint an agent, the Purchaser shall be entitled to appoint one on the relevant Seller's behalf at the relevant Seller's expense and shall promptly notify the relevant Seller of such appointment. Any claim form, judgment or other notice of legal process shall be sufficiently served on the Sellers, if delivered to the relevant agent at its address for the time being. Each Seller undertakes not to revoke the authority of the above agent unless it has:

- (i) obtained the consent of the Purchaser; and
- (ii) appointed another agent with an address in England and provided details of such agent to the Sellers' Representatives.

25.2 The Purchaser irrevocably appoints [***] of [***] as its agent to receive on its behalf in England or Wales service of any proceedings arising out of or in connection with this Agreement. Such service shall be deemed completed on delivery to that agent (whether or not it is forwarded to and received by the Purchaser). If for any reason that agent ceases to be able to act as agent or no longer has an address in England or Wales, the Purchaser shall promptly appoint another person as a replacement agent and shall give notice to the Sellers' Representatives of the new agent's name and address within England and Wales.

25.3 [***] shall as soon as reasonably practicable following the date of this Agreement (but, in any event, prior to Completion) appoint an agent with an address in England or Wales to receive on [***] behalf in England or Wales service of any proceedings arising out of or in connection with this Agreement. Such service shall be deemed completed on delivery to that agent (whether or not it is forwarded to and received by [***]). If for any reason that agent ceases to be able to act as agent or no longer has an address in England or Wales, [***] shall promptly appoint another person as a replacement agent and shall give notice to the Purchaser of the new agent's name and address within England and Wales.

26. Sellers' Representatives

26.1 Each of the Sellers (excluding the Institutional Sellers):

- (a) subject to sub-clause 25.1, agrees that:

- (i) any notice or other document which the Purchaser wishes to deliver to the Sellers (excluding the Institutional Sellers) or any of them arising out of or in connection with this Agreement may be delivered to them by being delivered to the Sellers' Representatives (excluding the Institutional Sellers' Representative);
- (ii) any notice, consent, agreement, direction or waiver required or permitted to be given or made by all or some of the Sellers (excluding the Institutional Sellers) (as the case may be) under this Agreement will be validly given or made on their behalf if given or made by the Sellers' Representatives (excluding the Institutional Sellers' Representative) for the purposes of this Agreement and will be binding on the relevant Sellers, as appropriate;
- (iii) the Purchaser shall be entitled to rely on all and any communications provided by the Sellers' Representatives (excluding the Institutional Sellers' Representative) which are expressed to be made for the purposes of this Agreement in good faith as binding on all or some of the Sellers (excluding the Institutional Sellers) (as the case may be);
- (iv) any communication in respect of any matter within the authority of the Sellers' Representatives (excluding the Institutional Sellers' Representative) described in this sub-clause 26.1 shall be deemed (unless the context otherwise requires) to be provided to the Sellers' Representatives (excluding the Institutional Sellers' Representative) as nominee for all or some of the Sellers (excluding the Institutional Sellers) (as the case may be) and any notice served on the Sellers' Representatives (excluding the Institutional Sellers' Representative) shall be deemed to have been validly served at the same time on each Seller (excluding the Institutional Sellers) on whom it is required to be served; and

- (b) authorises the Sellers' Representatives (excluding the Institutional Sellers' Representative) as their agent to:

- (i) act in the way contemplated by this Agreement and to take any decision as they may deem fit in their absolute discretion;

- (ii) enter into the Paying Agent Agreements on behalf of the Sellers, in such form as the Sellers' Representatives (excluding the Institutional Sellers' Representative) shall agree; and
- (iii) assume liability towards [***] under the Paying Agent Agreements on behalf of each of the Sellers (excluding the Institutional Sellers),

provided that the Sellers' Representatives (excluding the Institutional Sellers' Representative) act in Good Faith;

- (c) irrevocably agrees that, in the absence of fraud, gross negligence or wilful misconduct, the Sellers' Representatives (excluding the Institutional Sellers' Representative) will have and accept no liability to the Sellers or to any other person in connection with or as a result of anything which the Sellers' Representatives (excluding the Institutional Sellers' Representative) do, refrain from doing or neglect or omits to do in connection with any matter contemplated by this Agreement and/or the Paying Agent Agreements; and
 - (d) severally undertake, in the absence of fraud, gross negligence or wilful misconduct on the part of the relevant Sellers' Representative, to indemnify the Sellers' Representatives (excluding the Institutional Sellers' Representative) from and against all actions, claims and proceedings and all losses, payments, liabilities and reasonably incurred costs and expenses suffered, made or incurred by them (in their capacity as the Sellers' Representatives) as a consequence of the performance in Good Faith of their duties, functions and/or role as Sellers' Representatives under this Agreement and the Paying Agent Agreements, provided that, in no event, shall the amount payable by a relevant Seller under this clause 26.1(d) exceed (i) the liability attributable to each relevant Seller pursuant to clause 5.3 of the Paying Agent Agreements and (ii) that Seller's pro-rata proportion of such liability calculated by reference to the number of Completion Shares held by that Seller immediately prior to Completion as against the total number of Completion Shares in issue at Completion held by all Sellers (excluding the Institutional Sellers).
- 26.2 The FME Shareholders may, on any one or more occasions, notify (acting by the majority by value of Consideration receivable by the FME Shareholders) the Purchaser that they have chosen a different person to be the FME Shareholders' Representative to replace the person or entities then acting as such. Any such notice shall, notwithstanding clause 26.1, be valid only if signed by (or on behalf of) the FME Shareholders (constituting the majority by value of Consideration receivable by the FME Shareholders) and otherwise shall be given in accordance with clause 24. The change in identity of the FME Shareholders' Representative shall take effect [***] Business Days after notice of the change is received by the Purchaser or (if later) on the date (if any) specified in the notice. Until any such notice is received by the Purchaser, the Purchaser shall continue to be entitled to give notices to, and to rely on notices given (and other actions taken) by, the last FME Shareholders' Representative of whom it had actual knowledge.
- 26.3 The Investor Sellers (excluding the Institutional Sellers) may, on any one or more occasions, notify (acting by the majority by value of Consideration receivable by the Investor Sellers (excluding the Institutional Sellers)) the Purchaser that they have chosen a different person to be the Investor Sellers' Representative to replace the person or entities then acting as such. Any such notice shall, notwithstanding clause 26.1, be valid only if signed by (or on behalf of) the Investor Sellers (constituting the majority by value of Consideration receivable by the Investor Sellers (excluding the Institutional Sellers)) and otherwise shall be given in accordance with clause 24. The change in identity of the Investor Sellers' Representative shall take effect [***] Business Days after notice of the change is received by the Purchaser or (if later) on the date (if any) specified in the notice. Until any such notice is received by the Purchaser, the Purchaser shall continue to be entitled to give notices to, and to rely on notices given (and other actions taken) by, the last Investor Sellers' Representative of whom it had actual knowledge.

27. Institutional Sellers' Representative

27.1 Each of the Institutional Sellers:

- (a) agrees that:
 - (i) any notice or other document which the Purchaser wishes to deliver to all Institutional Sellers arising out of or in connection with this Agreement may, where specifically permitted under this Agreement, be delivered to them by being delivered to the Institutional Sellers' Representative;
 - (ii) any notice, consent, agreement, direction or waiver required or permitted to be given or made by all Institutional Sellers under this Agreement will be, where specifically permitted under this Agreement, validly given or made on

their behalf if given or made by the Institutional Sellers' Representative for the purposes of this Agreement and will be binding on the Institutional Sellers, as appropriate;

- (iii) the Purchaser shall, where specifically permitted under this Agreement, be entitled to rely on all and any communications provided by the Institutional Sellers' Representative which are expressed to be made for the purposes of this Agreement in good faith as binding on all Institutional Sellers;
 - (iv) any communication in respect of any matter which is specifically indicated in this Agreement to be within the authority of the Institutional Sellers' Representative shall be deemed (unless the context otherwise requires) to be provided to the Institutional Sellers' Representative as nominee for all Institutional Sellers and any notice served on the Institutional Sellers' Representative in such instances shall be deemed to have been validly served at the same time on each Institutional Seller on whom it is required to be served; and
- (b) authorises the Institutional Sellers' Representative to act in the way contemplated by this Agreement and agreement referred to in sub-clause 27.3 and, provided [***] acts in Good Faith, the Institutional Sellers' Representative will have and accepts no liability to the Institutional Sellers or to any other person in connection with or as a result of anything which the Institutional Sellers' Representative does, refrains from doing or neglects or omits to do in connection with any matter relating to this Agreement.

27.2 The Institutional Sellers may, on any one or more occasions, notify (acting jointly on a unanimous basis) the Purchaser that they have chosen a different person to be the Institutional Sellers' Representative to replace the person or entities then acting as such. Any such notice shall, notwithstanding clause 26.1, be valid only if signed by (or on behalf of) all Institutional Sellers and otherwise shall be given in accordance with clause 24. The change in identity of the Institutional Sellers' Representative shall take effect [***] Business Days after notice of the change is received by the Purchaser or (if later) on the date (if any) specified in the notice. Until any such notice is received by the Purchaser, the Purchaser shall continue to be entitled to give notices to, and to rely on notices given (and other actions taken) by (in each case, where specifically so permitted under this Agreement), the last Institutional Sellers' Representative of whom it had actual knowledge.

27.3 The Institutional Sellers and the Institutional Sellers' Representative further agree that, as soon as practically possible following the date of this Agreement (but, in any event, prior to Completion), they shall enter into an agreement regulating the rights and obligations of the parties to it in relation to the Institutional Sellers' Representative's role in connection with this Agreement, which shall be on terms to be agreed between the parties thereto (each acting reasonably), and which shall include (among other things) provisions whereby:

- (a) the Institutional Sellers' Representative shall:
 - (i) keep the Institutional Sellers fully updated and promptly share all relevant documents with them within the specified timeframes;
 - (ii) endeavour to give the Institutional Sellers the opportunity to provide comments on any relevant matters (subject to reasonable limited exceptions, for example requiring any urgent action on the side of the Institutional Sellers' Representative);
 - (iii) relate to the Purchaser any reasonable comments provided by the Institutional Sellers; and
 - (iv) subject to the Institutional Sellers' Representative acting in Good Faith in carrying out [***] role as the Institutional Sellers' Representative, have and accept no liability to the Institutional Sellers or to any other person in connection with or as a result of anything which the Institutional Sellers' Representative does, refrains from doing or neglects or omits to do in connection with any matter relating to this Agreement;
- (b) the Institutional Sellers shall:
 - (i) consider any requests of the Institutional Sellers' Representative as soon as reasonably practicable and, in any event, within the period of time, which will be sufficient for the Institutional Sellers to comply with any timing requirements under this Agreement;
 - (ii) act reasonably and provide reasons for any proposed action or inaction, along with suggestions as to steps which may be taken in order for consent to be provided or matters agreed; and

(iii) otherwise provide clear and consistent instructions to the Institutional Sellers' Representative.

28. Governing law and jurisdiction

28.1 This Agreement and any dispute, claim or obligation (whether contractual or non-contractual) arising out of or in connection with it, its subject matter or formation shall be governed by English law.

28.2 The parties irrevocably agree that the English courts shall have exclusive jurisdiction to settle any dispute or claim (whether contractual or non-contractual) arising out of or in connection with this Agreement, its subject matter or formation.

In witness whereof the parties or their duly authorised representatives have executed this Agreement as a deed and delivered it at the date first appearing at the head of this Agreement.

Schedule 1
(The Sellers)
Part 1
(The FME Shareholders)

[**]

Part 2
(The Investor Sellers)

[**]

Schedule 2
Part 1
(The Company)

Company name	InstaDeep Ltd
Registered number	09816291
Date of incorporation	8 October 2015
Place and jurisdiction of incorporation	England & Wales
Address of registered office	5 Merchant Square, London, England, W2 1AY
Issued share capital at Exchange (Warranted as at the date of this Agreement)	£2.571256 divided into: 1,529,184 Ordinary Shares of £0.000001 each 289,048 Class A Shares of £0.000001 599,171 Class B of £0.000001 each and 153,853 non-Voting Ordinary Shares (Employee Shares) of £0.000001 each
Charges	None
Loan capital	None
Directors	Afif Baccouche Arnaud Sylvain Barthelemy Karim Beguir Khaled Ben Jilani Zohra Slim Victorien Vaney
Secretary	Karim Beguir
Accounting reference date	31 December
Auditors	Shipleys LLP, 10 Orange Street, Haymarket, London, WC2H 7DQ
Tax residence	United Kingdom

Part 2
(The Group Companies (and branches))

Company name	InstaDeep SARL
Registered number	B0187762014, unique identifier: 1347719P
Date of incorporation	23 April 2014
Place of incorporation	Tunisia
Address of registered office	Immeuble ICC3 bloc D 4ème étage, Centre Urbain, Nord Tunis 1082
Issued share capital	TND 5,000
Charges	None
Loan capital	None
Directors	Zohra Slim (Gérante)
Secretary	N/A
Accounting reference date	31 December
Auditors	Cabinet Hatem Ben Naji - 3 avenue Louis Braille Tunis 1002. From 2022 accounts, auditors are Grant Thornton Tunisia, Promed Building, 5th floor, Centre Urbain Nord, 1082, Tunis
Tax residence	Tunisia
Shareholder(s) at Exchange (Warranted as at the date of this Agreement)	499 Shares – the Company 1 share – [***]
Shareholder(s) at Completion (Warranted as at Completion)	500 Shares – the Company

Company name	InstaDeep SAS
Registered number	842469918 RCS Paris
Date of incorporation	20 September 2018
Place of incorporation	France
Address of registered office	40 bis, rue du Faubourg Poissonnière, 75010 Paris, France
Issued share capital	€100,000 divided into 100,000 shares of €1.00 each
Charges	None
Loan capital	None
Directors	Karim Beguir (Président) and Isabelle Levard (Directrice Général)
Secretary	N/A
Accounting reference date	31 December
Auditors	Cabinet Caderas Martin - 43, rue de Liège 75008 Paris
Tax residence	France
Shareholder(s)	The Company

Company name	InstaDeep Nigeria Limited
Registered number	1563821
Date of incorporation	26 February 2019
Place of incorporation	Lagos, Nigeria
Address of registered office	7, Ibiyinka Olorube, Victoria Island, Lagos State, Nigeria
Issued share capital	NGN 10,000,000 divided into 10,000,000 shares of NGN 1 each
Charges	None
Loan capital	None
Directors	Karim Beguir Zohra Slim Isabelle Levard
Secretary	GFS Corporate Services Limited, 5th Floor, NCR Building, 6 Broad Street, Lagos
Accounting reference date	31 December
Auditors	Pedabo Audit Services - 67, Norman Williams Street - Ikoyi Lagos
Tax residence	Nigeria
Shareholder(s) at Exchange (Warranted as at the date of this Agreement)	9,990,000 – the Company 10,000 – [***]
Shareholder(s) at Completion (Warranted as at Completion)	9,990,000 shares – the Company 10,000 shares – InstaDeep SAS.

Company name	InstaDeep South Africa (branch)
Registered number	2020 / 052350 / 10
Date of incorporation	29 January 2020
Place of incorporation	Cape Town, South Africa
Address of registered office	80 Stand Street, Cape Town 8001, South Africa
Issued share capital	N/A
Charges	None
Loan capital	None
Directors	Zohra Slim Khaled Ben Jilani Karim Beguir Afif Baccouche
Secretary	Karim Beguir (InstaDeep Ltd)
Accounting reference date	31 December
Auditors	SJ Kruger - PO Box 264 Ferndale 2160
Tax residence	South Africa
Shareholder(s)	N/A (branch of the Company)

Company name	InstaDeep Dubai (branch)
Registered number	97028
Date of incorporation	17 February 2020
Place of incorporation	United Arab Emirates, Dubai
Address of registered office	Dubai Internet City, Premises EO 03, Ground Floor Building 07, Dubai,
Issued share capital	N/A
Charges	None
Loan capital	None
Directors	N/A
Secretary	Karim Beguir (InstaDeep Ltd)
General manager	Maher Mansour
Accounting reference date	31 December
Auditors	N/A
Tax residence	United Arab Emirates, Dubai
Shareholder(s)	N/A

Company name**InstaDeep DE GmbH**

Registered number	Amtsgericht Berlin (Charlottenburg), HRB 243790
Date of incorporation	11 May 2022
Place of incorporation	Berlin, Germany
Address of registered office	Stresemannstrasse 123 - 10963 Berlin
Issued share capital	€25,000
Charges	None
Loan capital	None
Directors	Isabelle Levard (Geschäftsführer)
Secretary	N/A
Accounting reference date	31 December
Auditors	N/A
Tax residence	Germany
Shareholder(s)	25,000 shares of EUR 1.00 each - InstaDeep SAS

Company name**InstaDeep LLC**

Registered number	37-2045700
Date of incorporation	11 March 2022
Place of incorporation	Dover (Delaware)
Address of registered office	874 Walker Road - Suite C - Dover 19904 (Delaware)
Issued share capital	\$100.00
Charges	None
Loan capital	None
Directors	Karim Beguir
Secretary	N/A
Accounting reference date	31 December
Auditors	N/A
Tax residence	United States of America
Shareholder(s)	100 Shares – the Company

Company name**InstaDeep Abu Dhabi (branch)**

Registered number	000007973
Date of incorporation	29 July 2022
Place of incorporation	Abu Dhabi
Address of registered office	DD-14-122-049-WeWork Hub71, 14, Al Khatem Tower, Adgm Sqaure, Al Maryah Island, Abu Dhabi, United Arab Emirates
Issued share capital	N/A
Charges	None
Loan capital	None
Directors	Karim Beguir Khaled Ben Jilani Zohra Slim Afif Baccouche Arnaud Sylvain Barthelemy Victorien Vaney
Secretary	Karim Beguir (InstaDeep Ltd)
General manager	Maher Mansour
Accounting reference date	31 December
Auditors	N/A
Tax residence	United Arab Emirates (Abu Dhabi)
Shareholder(s)	N/A (branch)

Schedule 3
(The Properties)
[***]

[**]

Schedule 4
(Non-Tax Warranties)

The Sellers

1. Arrangements with Seller Associates

Save in relation to employment contracts in relation to any Seller which have been Disclosed, there are no contracts, arrangements or liabilities, actual or contingent, outstanding or remaining in whole or in part to be performed between the Company and any Seller Associate.

2. Other interests of any Seller Associate

So far as the Warrantors are aware, no FME Shareholder has any interest, direct or indirect, in any business which has a close trading relationship with or which competes with any business now carried on by the Company and, so far as the Warrantors are aware, no Seller Associate of any FME Shareholder has or intends to do so.

3. Nomination agreements

So far as the Warrantors are aware, there is no nomination or other agreement, arrangement or commitment outstanding pursuant to which any person (other than the Sellers in relation to the Shares held by them respectively) is entitled to enjoy or exercise all or any rights of any kind in relation to the Shares pursuant to Section 145, CA2006 or the articles of association of the Company.

4. Brokerage, commission and other fees

No person is entitled to receive from the Company any introduction fee, brokerage or other commission in connection with the sale of the Completion Shares.

5. Interests in undertakings

5.1 Schedule 2 contains accurate details of all Group Companies and overseas branches.

5.2 The Company does not have, nor has it ever had, a participating interest (as defined in paragraph 11 of Schedule 10 of The Large and Medium sized Companies and Groups (Accounts and Directors' Report) Regulations 2008) in any undertaking or in the share capital of any body corporate which is not a Group Company nor has it agreed to acquire such an interest.

5.3 The Exchange Shares set out opposite each Seller's name in Schedule 1 (*The Sellers*), together with the BioNTech Company Shares, constitute the whole of the issued share capital of the Company at the date of this Agreement. The Completion Shares set out opposite each Seller's name in Schedule 1 (*The Sellers*), together with the BioNTech Company Shares, will comprise the whole of the issued share capital of the Company at Completion.

5.4 Except as set out in Schedule 2, the Company is the sole legal and beneficial owner of the whole of the allotted and issued share capital of each of the Group Companies (save for the Company) and the allotted and issued shares of the Group Companies are fully paid up (or credited as fully paid) and are free from any Encumbrance.

5.5 The Company is the true and lawful beneficial and record owner of [***] shares of Series Seed-1 Preferred Stock (the "[***] Shares") of [***] (collectively with any predecessor or successor entity thereof, "[***]"), free and clear of all Encumbrances. The [***] Shares constitute the Company's entire equity or ownership interest in [***], and other than the [***] Shares, the Company does not own any interest in [***], including without limitation, any debt or security exercisable for or convertible into an equity or ownership interest in [***].

5.6 No action, arbitration, suit, proceeding or investigation against the Company is pending, or so far as the Warrantors are aware, threatened against the Company, in relation to the Company's ownership of the [***] Shares.

5.7 No dividend, interim dividend, or other distribution, whether paid or still outstanding, has been declared or paid in relation to the [***] Shares, nor is there any other right outstanding to a distribution from or payment based upon reserves or profits of [***].

5.8 There are no current liabilities of any Group Company arising from any Group Company purchasing, selling, exercising, converting, making any agreement in connection with, or being a holder of, any equity interest or other security of [***].

5.9 Apart from this Agreement, the Options and the subsisting awards made under the French Plan, there is no agreement, arrangement or commitment outstanding which calls for the allotment, issue or transfer of, or accords to any person the right to call for the allotment, issue or transfer of, any share or loan capital of the Company.

- 5.10 No Group Company resides, operates or has any branch, agency, place of business or establishment outside the country or state in which it was incorporated.
- 5.11 The Company and each Group Company is incorporated and validly subsisting under the laws of its country of incorporation and is licensed or qualified to do business under the laws of that country.
- 5.12 No Group Company is, in relation to any company, limited liability partnership or Societas Europaea registered in the UK, (other than another Group Company), a registrable relevant legal entity within the meaning of section 790C, CA2006.
- 5.13 The Company has full corporate power to carry on its business and to own and operate its assets, properties and business as now carried on and owned and operated.

Corporate matters

6. Insolvency

- 6.1 No order has been made, no resolution has been passed, no petition presented, no meeting convened for the winding up of the Company or for a provisional liquidator to be appointed in respect of the Company and the Company has not been a party to any transaction which could be avoided in a winding up.
- 6.2 No administration order has been made and no petition for one has been presented in respect of the Company.
- 6.3 No administrator, receiver or administrative receiver has been appointed in respect of the Company or any of its assets.
- 6.4 The Company is not insolvent, has not failed nor is unable to pay any of its debts as they fall due, within the meaning of Section 123, Insolvency Act 1986.
- 6.5 No voluntary arrangement has been proposed under Sections 1, 256A or 263A, Insolvency Act 1986 in respect of the Company and the Company has not made or proposed any arrangement or composition with its creditors or any class of them.
- 6.6 No distress, execution or other process has been levied on the Company's assets or action taken to repossess goods in the possession of the Company.
- 6.7 No unsatisfied judgment is outstanding against the Company and no demand has been served on the Company under Section 123(1)(a), Insolvency Act 1986.
- 6.8 No event analogous to any referred to in sub-paragraphs 6.1 to 6.7 (inclusive) has occurred in any Applicable Jurisdiction.
- 6.9 InstaDeep SAS is not insolvent (*en état de cessation des paiements*), nor subject to any bankruptcy, insolvency, moratorium with creditors, conciliation procedure (*procédure de conciliation*) or similar proceedings under Applicable laws.

7. Statutory books and documents filed

- 7.1 The statutory books, including all registers and minute books, of each Group Company have been properly kept and are up to date and contain an accurate and complete record of the matters with which those books should deal with in accordance with Applicable Law.
- 7.2 All documents which should have been delivered by the Company to the Registrar of Companies in England and Wales or any relevant authority charged with maintaining a company's (or branch's) registry in any Applicable Jurisdiction are complete and accurate and have been properly so delivered.
- 7.3 The most recent copy of the articles of association of the Company that is available on Companies House is the current articles of association of the Company and has been Disclosed.
- 7.4 Since the Accounts Date the members of the Company in general meeting, or of any class of them, have not passed any resolution other than resolutions relating to the ordinary business of annual general meetings.

Information

8. Accuracy and adequacy of information

The information contained in columns C1 to E5 (inclusive) of Part 1 of Schedule 1, columns C1 to C4 (inclusive) of Part 2 of Schedule 1, Schedule 2 and Schedule 3 is accurate and complete.

Accounts

9. Preparation and contents of the Accounts

9.1 The Accounts:

- (a) have been prepared in accordance with the requirements of Applicable Law and all applicable accounting principles, methods and practices generally accepted and current at the Accounts Date in the jurisdiction in which, in the case of each Group Company, that Group Company was incorporated and, where the accounting practice used to prepare the Accounts differs from those applicable in the previous financial period, the effect of such differences has been Disclosed;
- (b) have been audited by a statutory or certified auditor (as applicable) who has rendered an auditor's certificate without qualification;
- (c) have been duly filed in accordance with the Applicable Law; and
- (d) have been Disclosed.

9.2 The Group Accounts as at the Accounts Date have been prepared in accordance with the requirements of Applicable Law and IFRS.

9.3 Without prejudice to the generality of sub-paragraph 9.1, the Accounts:

- (a) give a true and fair view of the state of affairs of each Group Company at the Accounts Date and the profits or losses of the Company for the financial period ending on that date in accordance with the relevant financial reporting framework;
- (b) contain proper provision or reserve for all liabilities and for all capital and revenue commitments of each Group Company as at the Accounts Date;
- (c) make proper provision for bad and doubtful debts; and
- (d) make proper provision for depreciation of the fixed assets of each Group Company having regard to their original cost and life.

9.4 The profits and losses of the Group shown in the Accounts were not, save as disclosed in the Accounts or in any note accompanying them, affected to a material extent by any transactions entered into otherwise than on normal commercial terms nor, to any material extent affected by any extraordinary, exceptional, unusual or non-recurring income, capital gain or expenditure or by any other factor known to the Warrantors rendering any such profit or loss for such period exceptionally high or low.

9.5 Except for obligations and liabilities reflected in the Accounts, the Group has no off balance sheet obligation or liability of any nature (matured or unmatured, fixed or contingent) to, or any financial interest in, any third party or entities, the purpose or effect of which is to defer, postpone, reduce or otherwise avoid or adjust the recording of debt expenses incurred by the Group.

9.6 The Group has established and maintains a system of adequate internal accounting controls sufficient to provide reasonable assurances that:

- (a) transactions are executed in accordance with the management's general or specific authorisation and to maintain accountability for assets; and
- (b) the amount recorded for assets on the books and records of the Group is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.
- (c) there are no significant deficiencies or material weaknesses in the design or operation of the Group's internal controls which could adversely affect the Group's ability to record, process, summarise and report financial data; and
- (d) there has been no change in the Group's accounting policies or estimation techniques since its incorporation, except as described in the Accounts or otherwise required by Applicable Law.

10. Accounting records

10.1 The accounting records of the Group comply with the requirements of Sections 386 and 388, CA2006 (whichever provision is applicable to the Company at the relevant time) or Applicable Law, do not contain any material inaccuracy or discrepancy and present in accordance with generally accepted accounting principles and standards the financial position of the Group.

10.2 All relevant financial books and records of the Group are in its possession or otherwise under its direct control.

11. Management Accounts

The Management Accounts have been Disclosed, and have been prepared in accordance with IFRS on a basis consistent with the Accounts, give a fair view of, and do not materially misstate, the financial and trading position of the Group as at their date and for the period to which they relate, and are not affected to a material extent by any extraordinary, exceptional, unusual or non-recurring income, capital gain or expenditure or by any other factor known by the Warrantors rendering profits or losses for the period covered exceptionally high or low.

12. Events since the Accounts Date

12.1 Since the Accounts Date:

- (a) there has not been any material deterioration in the financial or trading position or prospects of any Group Company; or
- (b) neither the turnover, direct or indirect expenses or the margin of profitability of any Group Company shows any material deterioration as compared with the position disclosed in the Accounts.

12.2 Since the Accounts Date, the Group has carried on its business in the ordinary course so as to maintain it as a going concern, and paid its creditors in the ordinary course and within the credit periods agreed with such creditors.

12.3 Since the Accounts Date, no supplier of any Group Company has ceased or restricted supplies or threatened in writing so to do, there has been no material loss or material curtailment of the business transacted by any Group Company with any customer which at any time in the preceding financial year represented [***]% or more of the turnover of any Group Company and the Warrantors are not aware of any circumstances likely to give rise to any of the above.

12.4 Since the Accounts Date, no Group Company has:

- (a) incurred or committed to incur:
 - (i) material capital expenditure in excess of £[***]; or
 - (ii) any liability whether actual or contingent except for full value or in the ordinary course of business;
- (b) acquired or agreed to acquire:
 - (i) any asset for a consideration higher than its market value at the time of acquisition or otherwise than in the ordinary course of business; or
 - (ii) any business or substantial part of it or any share or shares in a body corporate;
- (c) disposed of, or agreed to dispose of, any of its assets except in the ordinary course of business and for full value;
- (d) repaid wholly or in part any loan except upon the due date or dates for repayment;
- (e) save for the Options that are to be exercised prior to Completion and awards granted under the French Plan, issued or allotted share or loan capital, increased its authorised share capital, purchased or redeemed any shares, reduced or reorganised its share capital or agreed to do so; or
- (f) declared, made or paid any distribution of profit.

12.5 None of the debts included in the Accounts or any of the debts subsequently arising has been the subject of factoring by any Group Company and the Warrantors are not aware of any circumstances which could result in any presently outstanding debt in excess of £[***] not being paid in full.

13. Liabilities

No Group Company has any liabilities (contingent or otherwise), except:

- (a) those which are properly shown, provided for or reserved against in the Accounts or the Management Accounts; and
- (b) those which have been incurred in the ordinary course of business consistent with past practice since the Accounts Date.

Finance and working capital

14. Financial commitments and borrowings

14.1 Details of all overdraft, loan and other financial facilities available to the Company have been Disclosed and the Company is not in material breach of any of their terms.

- 14.2 The Company is not a party to, nor has agreed to enter into, any lending, or purported lending, agreement or arrangement (other than agreements to give credit in the ordinary course of its business).
- 14.3 The Company is not exceeding any borrowing limit imposed upon it by its bankers, other lenders, its articles of association or otherwise nor has the Company entered into any commitment or arrangement which might lead it so to do.
- 14.4 No overdraft or other financial facilities available to the Company are dependent upon the guarantee of or security provided by any other person.
- 14.5 So far as the Warrantors are aware, no event has occurred that with the passing of any time or the giving of any notice, certificate, declaration or demand, would constitute an event of default under, or breach of, any of the terms of any loan capital, borrowing, debenture or financial facility of the Company or which would entitle any person to call for repayment prior to normal maturity.
- 14.6 The company is not, nor has it agreed to become, bound by any guarantee, indemnity, surety or similar commitment.
- 14.7 The Company does not have any credit cards in issue in its own name or that of any officer or employee of the Company or any person connected with any officer or employee.
- 14.8 The Company has not received any grants, allowances, loans or financial aid of any kind from any government department or other board, body, agency or authority which may become liable to be refunded or repaid in whole or in part as a result of the entry into this Agreement.
- 14.9 The Company has not engaged in financing of a type which is not required to be or has not been shown or reflected in the Accounts.

15. **Working capital**

Having regard to existing bank and other facilities available to it, the Company has sufficient working capital for the purposes of carrying on its business, in its present form and at its present level of turnover.

Insurances

16. **Insurance cover**

- 16.1 The Company maintains, and at all times has maintained, adequate insurance cover against all risks normally insured against by companies carrying on a similar business on the same scale as the Company, having regard to the type of business carried on by the Company, its contractual commitments, location and assets owned or used by it, and in particular has maintained all insurances required by statute.
- 16.2 All of the insurance policies maintained by the Company are valid and enforceable and all premiums due have been paid. There are no outstanding claims or, so far as the Warrantors are aware, circumstances likely to give rise to a claim under such insurance policies or which would be required to be notified to the insurers and nothing has been done or omitted to be done which has made or could make any of the policies void or voidable or as a result of which the renewal of any such policy might be refused or the premiums due in respect of them may be liable to be increased (other than by a factor affecting the market as a whole).

17. **Insurance claims**

There are no claims outstanding or threatened in writing or, so far as the Warrantors are aware, pending, against the Company which are not fully covered by insurance.

Trading and contracts

18. **Contracts and commitments**

- 18.1 For the purposes of this paragraph 18:

"Key Client" means each of

[**]

"Key Supplier" means each of:

[**]

- 18.2 All contracts, agreements, transactions, obligations, commitments, understandings or arrangements (including, in each case, confirmation of whether such is with a client or supplier, as applicable) with Key Clients and Key Suppliers requiring in relation to its discharge any payment in excess of £[**] to which the Company is a party ("**Key Agreements**") are Disclosed and remain in full force and effect.

- 18.3 The Company is not a party to any material agreement, arrangement or commitment which:
- (a) has or is expected to have, so far as the Warrantors are aware, material consequences in terms of expenditure or revenue, other than in the ordinary course of business;
 - (b) can be terminated in the event of entry into or completion of this Agreement;
 - (c) relates to matters outside its ordinary business or was not entered into on arms' length terms;
 - (d) so far as the Warrantors are aware, cannot readily be fulfilled or performed on time; or
 - (e) cannot be terminated, without giving rise to any material liabilities on it, by it giving [***] months' notice or less.
- 18.4 The Company has no outstanding bid, tender, sale or service proposal which is material in relation to its business.
- 18.5 The Company has not granted any power of attorney or other such authority which is still outstanding, other than ordinary course authorities at the Group Company level.
- 18.6 So far as the Warrantors are aware, no act or omission by the Company has caused it to be in material default of any Key Agreement and the Warrantors are not aware of any actual breach, invalidity, grounds for termination, grounds for rescission, grounds for avoidance or grounds for repudiation of, any Key Agreement.
- 18.7 The Warrantors are not aware that any Key Client of the Company has withdrawn or is considering withdrawing from or not placing with the Company all or any part of the work placed with the Company during the [***] months immediately preceding the date of this Agreement.
- 18.8 No matter has arisen in respect of any Key Agreement which, so far as the Warrantors are aware, is or could result in a breach by any party thereto.
- 18.9 There have been no material written complaints within the last [***] made by any party thereto in respect of any Key Agreement and the Company has received no written notice of any default under any Key Agreement.
- 18.10 Within the [***] months preceding the date of this Agreement no surcharges have been levied or arisen with regard to any expenditure whether due to delay in payment by any Key Client of any sums due in respect thereof or otherwise.
- 18.11 No Key Client has sought to negotiate a reduction or material change in the terms of remuneration as contained in its Key Agreement with the Company.
- 18.12 There is not outstanding any contract or arrangement to which the Company is a party and to which any director of the Company is interested whether directly or indirectly.
- 18.13 In respect of the services agreement between the Company and InstaDeep SAS, dated [***]:
- (a) no party other than a Group Company has any rights or obligations pursuant to or under the terms of this agreement; and
 - (b) such agreement has been agreed and conducted in accordance with a transfer pricing policy implemented by the Group, which is adequate for a business of the same size and type.
- 18.14 The Company is not, and has not at any time, engaged in any activity, practice or conduct which would constitute an offence under:
- (a) the Bribery Act 2010; or
 - (b) an Applicable Law relating to anti-bribery or anti-corruption in any jurisdiction, including, so far as the Warrantors are aware, in respect of the Company's relationship with [***].
- 18.15 So far as the Warrantors are aware, no Company Associate has bribed another person (within the meaning of Section 7(3), Bribery Act 2010) intending to obtain or retain business or an advantage in the conduct of business for the Company.
- 18.16 The Company has had in place, at all times in the [***] preceding the date of this Agreement, such procedures as it is reasonable in all circumstances to expect it to have designed to prevent Company Associates from bribing another person (within the meaning of Section 7(3), Bribery Act 2010) intending to obtain or retain business or an advantage in the conduct of business for the Company and/or any Group Company.
- 18.17 For the purposes of this paragraph 18, "**Company Associate**" means any person who performs services (within the meaning of Section 8, Bribery Act 2010) for or on behalf of the

Company and the meaning of "adequate procedures" shall be determined in accordance with Section 7(2), and any guidance issued under Section 9, Bribery Act 2010.

19. **Trading partners**

- 19.1 The Company does not act or carry on business in partnership with any other person and is not a member of any corporate or unincorporated body, undertaking or association.
- 19.2 The Company is not a party to any joint venture agreement or arrangement under which it is to participate with any other person in any business.
- 19.3 The Company is not a party to any agency, distributorship, licence or management agreement which restricts its freedom to carry on its business in such manner as it may think fit.
- 19.4 The Company is not, nor has it agreed to become, a party to an agreement or arrangement for sharing commissions or other income.

20. **Licences and consents**

- 20.1 All licences, consents, permissions, authorisations and approvals required by the Company for the carrying on of its business in the places and in the manner in which its business is now carried on have been obtained by it and are in full force and effect.
- 20.2 All reports, returns and information required by Applicable Law or as a condition of any licence, consent, permission, authorisation or approval to be made or given to any person or authority in connection with the business of the Company have been made or given to the appropriate person or authority and so far as the Warrantors are aware, there are no circumstances which indicate that any licence, consent, permission, authorisation or approval might not be renewed in whole or in part or is likely to be revoked, suspended or cancelled or which may confer a right of revocation, suspension or cancellation.

21. **Competition and trade regulation law**

- 21.1 The Company is not nor has it been a party to any agreement, arrangement, understanding or concerted practice during the [***] preceding this Agreement:
 - (a) which infringes, or has infringed, any applicable competition law;
 - (b) in respect of which any filing, registration or notification is, was or will be required by, or is, was or will be advisable pursuant to, any applicable competition law (whether or not the same has in fact been made);
 - (c) which is, or was, the subject of an investigation under any applicable competition law; or
 - (d) in connection with which it is or has been subject to any orders or directions, or has given any undertakings or commitments or assurances under any applicable competition law.
 - 21.2 The Warrantors have no reason to believe that any action or investigation under any applicable competition law is being or will be taken against the Company in relation to any of its current activities.
 - 21.3 The Company has not during the [***] preceding this Agreement made any complaint against any other person in relation to alleged infringements of any applicable competition law.
 - 21.4 For the purposes of this paragraph 21, the term "**applicable competition law**" means all competition law applicable to the business carried on by the Company, whether of the United Kingdom, the European Union or any other jurisdiction, and includes (but is not limited to) any applicable rules dealing with anti-competitive agreements, arrangements or practices, abuse of dominant position, state aid, public procurement, merger control or anti-dumping, and the requirements of any special regulatory regime to which the business carried on by the Company may be subject in any area of its activities.
22. **Compliance with law**
- 22.1 The business of the Company has at all times been conducted in all material respects in accordance with all Applicable Laws, including applicable Sanctions.
 - 22.2 The Company has not committed and no claim has been made in writing that it has committed any criminal, illegal, unlawful or unauthorised act or breach of any obligation or duty imposed by Applicable Law, including applicable Sanctions.
 - 22.3 So far as the Warrantors are aware, no investigation or inquiry is being, or has in the last [***] been, conducted by, and the Warrantors have not received any request for information from any Governmental Authority in respect of the Company's affairs and, so far as the Warrantors are aware, there are no circumstances which would give rise to such investigation, inquiry or request.

- (a) For the purposes of this paragraph 22, "**Sanctions**" means any trade, economic or financial sanctions laws, regulations, embargoes or restrictive measures administered, enacted or enforced by any of (a) the Security Council of the United Nations; (b) the United States of America; (c) the European Union; (d) the United Kingdom; (e) the governments and official institutions or agencies of any of paragraphs (a) to (d), including without limitation, the Office of Foreign Assets Control of the US Department of the Treasury; the US Department of State and Her Majesty's Treasury.

23. Litigation and disputes

- 23.1 Except for actions to recover any debt incurred in the ordinary course of the business owed to the Company where each individual debt and its costs outstanding amount to less than £[***]:
- (a) neither the Company nor, so far as the Warrantors are aware, any person for whose acts the Company may be liable is engaged in any litigation, arbitration, administrative or criminal proceedings, whether as claimant, defendant or otherwise;
 - (b) no litigation, arbitration, administrative or criminal proceedings by or against the Company or any person for whose acts it may be liable are threatened or expected and, as far as the Warrantors are aware, none are pending; and
 - (c) so far as the Warrantors are aware, there are no facts or circumstances likely to give rise to any litigation, arbitration, administrative or criminal proceedings against the Company or any person for whose acts it may be liable.
- 23.2 Full details of [***] have been Disclosed.
- 23.3 The Company is not subject to any outstanding order or judgment given by any court or Governmental Authority and has not been a party to any undertaking or assurance given to any court or governmental or other authority, department, board, body or agency which is still in force, nor so far as the Warrantors are aware are there any facts or circumstances likely to give rise to it becoming subject to such an order or judgment.

Assets

24. Ownership and condition of assets

- 24.1 Each of the assets included in the Accounts or acquired by the Company since the Accounts Date (other than the Properties and current assets subsequently disposed of or realised in the ordinary course of business) is either owned by the Company free from Encumbrance (save in respect of liens arising in the normal course of trading) or is legally in its possession or under its control.
- 24.2 So far as the Warrantors are aware, each item of plant and machinery, vehicle and office equipment used by the Company is:
- (a) in good repair and condition, regularly maintained and, where required by law, certified safe and without risk to health when used;
 - (b) capable of doing the work for which it was designed or purchased; and
 - (c) not surplus to requirements.
- 24.3 The Company has not acquired, or agreed to acquire, any assets on terms that title to the asset does not pass until full payment is made or all indebtedness incurred in connection with the acquisition is discharged.
- 24.4 A summary of the assets owned by the Company, together with details of all assets held under hire purchase, lease or rental agreements, have been Disclosed and such assets comprise all assets necessary for the continuation of the business of the Company as it is currently carried on.

25. Charges and Encumbrances over assets

- 25.1 No Encumbrance (other than a lien arising by operation of law in the ordinary course of trading) or other form of security or encumbrance or equity on, over or affecting the Completion Shares or the whole or any part of the undertaking or assets of the Company, including any investment in any other company, is outstanding and, apart from this Agreement, there is no agreement or commitment to give or create any of them and no claim has been made by any person to be entitled to any of them.
- 25.2 No floating charge created by the Company has crystallised and, so far as the Warrantors are aware, there are no circumstances likely to cause such a floating charge to crystallise.
- 25.3 The Company has not received notice from any person intimating that it will enforce any security which it may hold over the assets of the Company, and so far as the Warrantors are aware, there are no circumstances likely to give rise to such a notice.

Intellectual Property

26. Details of Intellectual Property

26.1 Details of all material Company Intellectual Property and copies of all licences and other agreements relating to it have been Disclosed.

26.2 All Company Intellectual Property is either:

- (a) in the sole legal and beneficial ownership of the Company free from all licences, charges or other encumbrances; or
- (b) the subject of binding and enforceable licences to the Company granted by third parties:
- (c) of which no notice to terminate has been received;
- (d) all parties to which have fully complied with all obligations in those licences; and
- (e) in relation to which no disputes have arisen or are foreseeable,

and in either case, so far as the Warrantors are aware, nothing has been or will be done or omitted to be done prior to the Completion Date whether by the Company or by any person which would jeopardise the validity, enforceability or subsistence of any Company Intellectual Property or any such licences.

26.3 The Founders, Senior Employees and any other employees, consultants, inventors or contributors involved in the development of Company Intellectual Property or any Group Company technology or any Group Company product or who otherwise provides material value in support of the Business as currently conducted have signed confidentiality and Intellectual Property rights assignment agreements or similar agreements for the transfer, assignment, or licensing of such Company Intellectual Property to the Company pursuant to which the Company has either (i) obtained ownership of and is the exclusive owner of; or (ii) obtained a valid and unrestricted right to exploit such Company Intellectual Property which is, so far as the Warrantors are aware, sufficient for the operation of the Business as currently conducted.

26.4 Commercially reasonable steps have been taken by each Group Company sufficient to maintain the confidentiality of any trade secret rights held by any Group Company, or purported to be held by any Group Company, as a trade secret.

26.5 The Group Companies own or otherwise have all Intellectual Property rights they need to conduct their business as currently conducted, and after the Completion Date, the Purchaser will have all rights to all Intellectual Property needed to materially conduct any Group Company's business as currently conducted.

27. Registration

27.1 Any Company Intellectual Property owned by the Company which is capable of registration has been registered or is the subject of an application for registration, and is or will when duly registered be valid, binding and enforceable and:

- (a) in the case of such registrations, all renewal fees have been paid, all renewals have been made by their due date and all such action necessary to preserve and maintain the registration has been taken;
- (b) in the case of such registrations, each is presently used by a Group Company and is in full force and effect and has not been abandoned;
- (c) in the case of pending applications, the Warrantors are aware of no reason why any such applications should not proceed to grant; and
- (d) none of the Company owned Company Intellectual Property or Company Intellectual Property that is exclusively licensed to the Company is subject to any use, claim, exploitation or attack by any other person, and none of the Company Intellectual Property that is non-exclusively licensed to the Company is subject to any claim, exploitation or attack by any other person.

28. Rights of third parties

28.1 No licences, registered user or other rights have been granted or agreed to be granted by the Company to any person in respect of any Intellectual Property.

28.2 The Group Companies do not use any Intellectual Property in respect of which any third party has any right, title or interest.

28.3 Each of the Group Companies own or have the unrestricted rights to use all Intellectual Property required in connection with the conduct of its business as currently conducted.

- 28.4 No Group Company is indebted to any employee (past or present) for any amount whatsoever related to inventor's compensation in respect of Company Intellectual Property and the Company has not received any notice of any such claim in respect of the same.
29. **Infringement and royalties etc.**
- 29.1 Since incorporation of the Company, so far as the Warrantors are aware, there has been no unauthorised use, misappropriation or infringement by any person of any Intellectual Property.
- 29.2 Since incorporation of the Company, no person has made any claim that there has been any unauthorised use, misappropriation or infringement by any person of any Company Intellectual Property.
- 29.3 So far as the Warrantors are aware, none of the processes employed, or products or services dealt in, by the Group Company infringes or misappropriates any rights of any third party relating to any Intellectual Property nor is any Group Company liable to pay a fee or royalty on that basis, and no claims have been made, threatened or, so far as the Warrantors are aware, are pending, in relation to any Intellectual Property against the Company. There is no legal proceeding threatened, or so far as the Warrantors are aware, pending against any of Group Company relating to any infringement or misappropriation of any Intellectual Property of another person by a Group Company.
30. **Information technology**
- 30.1 All contracts, agreements, transactions, obligations, commitments, understandings or arrangements between the Company and:
[***]
(together, the "**Material IT Agreements**" and each a "**Material IT Agreement**"),
have been Disclosed, remain in full force and effect and such contracts, agreements, transactions, obligations, commitments, understandings or arrangements do not deviate from those typically accepted in the Company's usual course or business, and so far as the Warrantors are aware, no act or omission by the Company or counterparty has caused such party to be in material default of any Material IT Agreement.
- 30.2 No act or omission by the Company has caused it to be in material default of any Material IT Agreement.
- 30.3 Details of the computer hardware, networks and software ("**IT Systems**") used by the Company as at the date of this Agreement have been Disclosed. So far as the Warrantors are aware, the IT Systems are the only information technology required by the Company to carry on its business as currently conducted.
- 30.4 There has been no failure or breakdown in the [***] months prior to the date of this Agreement of any IT Systems used by the Company that has caused any material disruption to the business of the Company or customer of the Company.
- 30.5 So far as the Warrantors are aware, the Company has implemented appropriate procedures in accordance with best industry practice (including in relation to off-site working where applicable) for ensuring the security of the IT Systems and the confidentiality and integrity of the Systems Data.
- 30.6 The Company has in place a data security breach plan and a disaster recovery plan which is fully documented which would enable the Business to continue if there were damage to or destruction of some or all of the IT Systems.
- 30.7 So far as the Warrantors are aware, during the three years period up to and including the date of this Agreement, the Company has not:
(a) breached any applicable data security breach or breach notification requirement under the Cybersecurity Requirements; or
(b) suffered any Security Incident.
31. **Disclosure of confidential information etc.**
Except in the ordinary course of business or on a confidential basis in connection with fundraising rounds and as required pursuant to this Agreement and the transactions contemplated by it, no disclosure has been made of any of the confidential information, know how, technical processes, financial or trade secrets or customer or supplier lists of the Company.
32. **Names**
Any names used by the Company have been Disclosed and, so far as the Warrantors are aware, do not infringe the rights of any person.

33. **Open Source Software**

- 33.1 The Company has Disclosed all Open Source Materials used in the Business and the Company has Disclosed all scans of Company software that includes any Open Source Material used in the Business.
- 33.2 Each Group Company has complied in all material respects with the terms of the Open Source Material licenses it uses or has used in the Business.
- 33.3 No Group Company's use of Open Source Material requires any redistribution of any software or of any Company Intellectual Property under terms that (i) require disclosure or distribution of any software or other Intellectual Property of Company to third parties; (ii) require the Company to license, sublicense or distribute any Company products for no consideration; or (iii) allow any third party to decompile, disassemble or reverse engineer any Company products.
- 33.4 The Company has not:
- (a) incorporated or combined Open Source Materials with the Intellectual Property; or
 - (b) distributed or licensed Open Source Materials in conjunction with any Intellectual Property.

Data Protection

34. **Compliance**

- 34.1 The definitions in this paragraph apply in this Agreement:

"Data Protection Laws" means any applicable laws and regulations in any relevant jurisdiction relating to the use or processing of personal data including (i) EU Regulation 2016/679 ("**GDPR**"); (ii) GDPR as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 (the "**UK GDPR**"); (iii) any laws or regulations ratifying, implementing, adopting, supplementing or replacing the GDPR; (iv) in the UK, the Data Protection Act 2018 ("**DPA**"); (v) any laws and regulations implementing or made pursuant to EU Directive 2002/58/EC (as amended by 2009/136/EC); and (vi) in South Africa, the Protection of Personal Information Act No 4 of 2013; (vii) in the UK, the Privacy and Electronic Communications (EC Directive) Regulations 2003; (viii) in France, the Law n°78-17 of 6 January 1978 on data processing, data files and individual liberties, and in each case, as updated, amended or replaced from time to time; and the terms "**Data Subject**", "**Personal Data**", "**processing**", "**processor**" and "**controller**" shall have the meanings set out in the DPA.

"Supervisory Authority" means any local, national, supranational, state, governmental or quasi-governmental agency, body, department, board, official or entity exercising regulatory or supervisory authority pursuant to any Data Protection Laws, including the Information Commissioner's Office in the UK.

- 34.2 The Company has, as regards to all personal data (as defined in the relevant Data Protection Laws) controlled and/or processed by it, complied in all material respects with all relevant requirements of the relevant Data Protection Laws, and has not been charged with or convicted of any offence under the Data Protection Laws.
- 34.3 The Company has:
- (a) appointed a data protection officer if required to do so under the Data Protection Laws, and details of such appointment are set out in the Disclosure Documents;
 - (b) carried out and maintained complete, accurate and up to date records of, all data protection impact assessments required by the Data Protection Laws; and
 - (c) put in place an adequate data breach response plan that enables the Company and the processors to comply with the related requirements of the Data Protection Laws, details of which are set out in the Disclosure Documents.
- 34.4 The transfer of all personal data by the Company outside of the United Kingdom or European Economic Area has, and so far the Warrantors are aware third party processors carrying out such transfers on the Company's behalf have, complied in all material respects with all Data Protection Laws, including all appropriate safeguards having been put in place.
- 34.5 In the previous [***] years, the Company has complied with all data subject requests, including any requests for access to Personal Data, the cessation of specified processing activities or the rectification or erasure of any Personal Data, in each case in accordance with the requirements of the Data Protection Laws, and no such requests are outstanding.

- 34.6 Neither the Company nor any of the Processors have, in the previous [***] years, suffered any breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to any Personal Data.
- 34.7 The Company has not in the previous [***] years received any:
- (a) written notice, request, correspondence or other communication from any Supervisory Authority, or been subject to any enforcement action (including any fines or other sanctions), in each case in writing relating to a breach or alleged breach of their obligations under the Data Protection Laws; or
 - (b) written claim, complaint, correspondence or other communication from a data subject or any other person claiming a right to compensation under the Data Protection Laws, or alleging any breach of the Data Protection Laws.
- 34.8 The Company has duly complied with all applicable notification or registration obligations and paid the appropriate level of fees or charges in respect of its processing activities, in each case as required by the Data Protection Laws.

Employment

35. Particulars of employees and workers

- 35.1 The key terms and conditions of employment of all employees of the Group by category, including, in anonymised form, the date of commencement of their continuous period of employment, their remuneration (including, without limitation, bonus, commission, overtime, profit sharing, share incentive, restricted shares, phantom, share option scheme, long term incentive, car, redundancy, permanent health insurance, medical expenses insurance, life assurance and pension benefits, benefit schemes, or any other payment, benefits or arrangements and understandings whatsoever payable to employees (the "**Schemes**")), job title, notice periods, holiday entitlement, sick pay entitlement, particulars of employment given to each employee pursuant to Section 1, Employment Rights Act 1996 (or as applicable in each relevant jurisdiction) and details of any current absence from work (including but not limited to secondments, maternity leave, paternity leave, adoption leave, shared parental leave, parental leave or absent for any other reason) have been Disclosed.
- 35.2 There are no proposals to introduce any Schemes save as Disclosed.
- 35.3 In respect of all persons who are consultants to or who otherwise provide their personal service to the Company (including, but not limited to, out workers, agency staff, self-employed persons, contractors, interims, locums, freelancers, secondees, zero-hours workers, contracted labour or agents) details of the terms of their engagement (whether with the Company or a third party supplier such as a staffing agency, a personal service company or some other supplier intermediary), including the date of commencement of the engagement of their services, the role they undertake, the average number of hours per week they provide services to the Company, the fees paid in respect of the services they supply, any other benefits (including but not limited to any benefits or arrangements under any Schemes) provided to them (whether or not legally binding), the notice period required to terminate the engagement or supply and any holiday arrangements have been Disclosed. The terms of engagement have been complied with by each Group Company and are in compliance with Applicable Laws.
- 35.4 True and complete copies of:
- (a) all contracts of employment and engagement of those employees and officers employed or engaged as a Senior Employee;
 - (b) any standard form employment contracts with the Company and which employees and/or officers they apply to;
 - (c) a copy of any non-standard form employment contracts not otherwise disclosed above and which employees and/or officers they apply to;
 - (d) all staff handbooks, employment policies and procedures relating to the employment of the employees;
 - (e) all consultancy agreements and letters of engagement relating to the engagement of consultants and workers; and
 - (f) all agreements with third party suppliers (including any staffing agencies) who supply the services of any of the supplied workers as disclosed under paragraph 35.3,
- have been Disclosed.
- 35.5 The Company is not a party to any agreement for management services or any contract for services with any director.

36. **Remuneration and incentives**

- 36.1 Details have been Disclosed of any arrangements or assurances as to future remuneration or benefits to be provided to any officer or employee, worker or consultant howsoever arising (including, but not limited to, any remuneration, agreements, Schemes, obligations or benefits to be provided as a consequence of this Agreement) or as to any compensation or payment to be made to any such person in the event of retirement, redundancy or other termination of employment however arising, however funded and whether or not legally binding.
- 36.2 Since the Accounts Date or (where the relevant employment commenced after the beginning of such period) since the commencing date of the particular employee's employment there has been:
- (a) no material alteration in the terms of employment and/or engagement or any material change in the number of officers, employees, workers or consultants employed and/or engaged by a Group Company; or
 - (b) no fees, earnings, remuneration or benefits paid or payable to any officer, employee, consultant or worker of a Group Company have increased by more than [***]%, nor are any negotiations for any increase in excess of [***]% current or likely to take place in the next [***] months in respect of the same.
- 36.3 No agreement has been reached or negotiations are current or anticipated to take place at any time within the period from the date of this Agreement to the date that is [***] months following Completion in relation to any decrease and/or variation in the remuneration, hours, incentive arrangements and/or benefits of officers, employees and/or workers of the Group Companies. In respect of any Disclosure against this warranty, any such agreement that has been reached and/or negotiations that have been started, have been carried out in accordance with the officers' employees' and workers' (as applicable) terms and conditions of employment or engagement and Applicable Laws.
- 36.4 In relation to all officers, employees and workers who are or have been placed on furlough leave (or equivalent in any relevant jurisdiction):
- (a) no Group Company has re-employed and/or re-engaged any person, or otherwise extended any notice period and/or fixed term contract of any person to enable them to participate in such furlough or other governmental job retention scheme (including, but not limited to, the CJRS);
 - (b) the reason for placing such person on furlough leave was wholly connected to the detrimental effects of Coronavirus on the reasonable need and/or ability of such a person to undertake their role for the relevant Group Company;
 - (c) no person has been given and/or has given notice to terminate their employment with any Group Company and/or otherwise been employed during their notice period at any time during which they were placed on furlough leave for the purposes of the CJRS;
 - (d) the Company has at all times complied with the Treasury Direction made under Sections 71 and 76 of the Coronavirus Act 2020 (in each case, as amended from time to time);
 - (e) each Group Company has complied with all government guidance (as amended from time to time) in respect of any furlough or other governmental job retention scheme;
 - (f) there are no circumstances in which it could be reasonably claimed that any Group Company's use of a furlough or other governmental job retention scheme in respect of any such person is abusive or is otherwise contrary to its exceptional purpose; and/or
 - (g) each Group Company has not submitted any dishonest, inaccurate and/or fraudulent information to HMRC (or equivalent body in each relevant jurisdiction) in respect of any such person;
 - (h) no worker has been placed on furlough and been paid using furlough or other governmental job retention scheme grant unless they were on the Company's payroll at the date required under the Treasury Direction made under Sections 71 and 76 of the Coronavirus Act 2020 (in each case, as amended from time to time); or
 - (i) provision has been made in the Company's accounts for payment of annual leave accrued during the furlough period in respect of any and each zero hours worker furloughed by the Company.
- 36.5 In the [***] months preceding Completion, the Company has at all times, insofar as required by Applicable Law, required employees, workers and officers of the Company to take any accrued but unused holiday entitlement in the relevant leave year. The Company has not permitted, nor is it aware of any such circumstances in which any employees, workers or officers of the

Company may claim that they are eligible to carry over any holiday entitlement in accordance with Working Time (Coronavirus) (Amendment) Regulations 2020.

- 36.6 The Company is not bound or accustomed to pay any monies other than in respect of contractual remuneration or earnings of employment to or for the benefit of any employee.
- 36.7 No agreement has been reached with any employee, trade union or other employee representative that will on a future date result in an increase in the rate of remuneration or enhanced benefits for any employee (including but not limited to, bonus or commission payments).
- 36.8 No negotiations for any increase in the remuneration or benefits of any employees is current or (based on past practice) anticipated to take place within [***] months after the date of this Agreement.
- 36.9 Other than salary for the current month and accrued holiday pay for the current holiday year, no amount is owing to any present or former officer, employee, worker or consultant of the Company in respect of the period up to the date of this Agreement.
- 36.10 There is not outstanding any agreement or arrangement to which the Company is party in relation to profit sharing or for payment of bonuses or for incentive payments or other similar matters.
- 36.11 Save for the Stock Option Plan and the French Plan and as disclosed in the Disclosure Documents, the Company does not operate (nor is the Company proposing to introduce) any share incentive, share option, restricted stock or phantom scheme, or any long term incentive plan, stock appreciation right, profit sharing, bonus, commission or other employees' share scheme or employee benefit trust for the benefit of all or any of its current or former directors or employees.
- 36.12 In relation to the Stock Option Plan:
- (a) details:
 - (i) of it (including copies of board minutes, the rules of the Stock Option Plan and any amendments thereto), together with details of the unique scheme reference number provided by HMRC on registration of the Stock Option Plan, copies of any advance assurance sought or obtained from HMRC, all annual returns filed with HMRC and any correspondence with HMRC Shares and Assets Valuation;
 - (ii) of all Options which have been granted to current or former employees and directors (including Options which have been surrendered, renounced or lapsed) and copies of all letters or agreements granting Options, forms of exercise and details of:
 - (A) the date of grant;
 - (B) the exercise price;
 - (C) the number of shares under option;
 - (D) the vesting terms; and
 - (E) any performance conditions;are contained in the Disclosure Documents;
 - (b) there have been no amendments to the terms of the Options;
 - (c) each EMI Option granted was notified to the applicable authorising body in the relevant jurisdiction within [***] days of the date of grant;
 - (d) none of the Options granted have been exercised (prior to the date of this Agreement);
 - (e) all registrations, notifications and declarations have been made to the applicable authorising body in the relevant jurisdiction within the relevant time period and no penalties have arisen or are expected to arise in respect of any such registrations, notifications and declarations;
 - (f) all EMI Options have been administered in accordance with the requirements of the Board of HMRC and ITEPA and in accordance with the powers and provisions contained in its rules and all applicable laws, regulations and requirements of any competent governmental body or regulatory authority; and
 - (g) no claim has been threatened or made or litigation commenced against the Company in respect of any matter arising out of or in connection with the Stock Option Plan and

so far as the Company is aware, there are no circumstances which may give rise to any such claim or litigation.

- 36.13 Save under the Stock Option Plan, no employment related securities (as defined in sections 420 and 421B(8), ITEPA) have been issued or transferred and no securities options (as defined in section 420(8), ITEPA) have been granted by the Company to any current or former employee or director, and there are no agreements or promises to make any such issues, transfers or grants.
- 36.14 There are no employee benefit trusts, family trusts or similar arrangements established by the Company and the Company is not aware of any relevant step taken by a relevant third party in respect of current or former employees or directors of the Company which would give rise to a liability under Part 7A of ITEPA.
- 36.15 All joint elections in respect of restricted securities made by the Company with current or former employees or directors under Chapter 2 of Part 7 of ITEPA have been properly made using forms approved by HMRC and within the applicable time limits.
- 36.16 Any shares issued or transferred or options granted over shares by the Company to employees or directors under the Stock Option Plan or as disclosed in the Disclosure Letter meet the requirements for the Company to obtain a deduction for corporation tax under Part 12 of the Corporation Tax Act 2009 (or would do so, but for the effects of Completion).
- 36.17 The agreements entered into between InstaDeep SAS and any of its employees and any other agreement between any InstaDeep SAS and one of its officers or directors currently in effect do not provide for indemnification, including indemnification in case of dismissal, exceeding the obligations provided for under the applicable collective bargaining agreements or applicable laws, nor do they provide for any contractual benefits beyond statutory requirements (*avantages particuliers exceptionnels*), including social benefits.
37. **Compliance**
- 37.1 Each Group Company has complied in all material respects with its obligations under Applicable Laws concerning the health and safety at work of its employees and workers and so far as the Warrantors are aware, there are no claims pending or threatened by any employee or third party in respect of any accident or injury which are not fully covered by insurance.
- 37.2 InstaDeep SAS has complied in all material respects with its obligations under Applicable Laws concerning employment and social security matters, the provisions of any collective bargaining agreements applying to it and/or to which it is a party, those relating to working hours and extra-hours, monitoring of working-time, overtime, disconnection (*droit à la déconnection*), the health and safety at work of its employees and workers, calculation and payment of social contributions, immigration, non-discrimination, work of disabled employees, regulations relating to the internal regulation (*règlement intérieur*), employee termination, as well as employee representation and so far as the Warrantors are aware, there are no claims pending or threatened by any employee or third party of any of such non-compliance.
- 37.3 In relation to each of the employees (and so far as relevant to each of its former employees) so far as the Warrantors are aware each Group Company has:
- (a) complied with all obligations imposed on it by all Applicable Laws relevant to the relations between it and any employee and any recognised trade union or other employee representative; and
 - (b) complied with all relevant orders and awards affecting the conditions of service of any employee.
- 37.4 InstaDeep Nigeria Limited has at all times complied in all material respects with its obligations in respect of the Nigeria Social Insurance Trust Fund ("**NSITF**") and provisions of the Nigerian Employees Compensation Act 2010, and all returns which are required to have been submitted in respect of the NSITF for the years 2020, 2021 and 2022 have been submitted to the NSITF Management Board on or before the relevant submission dates.
- 37.5 InstaDeep Tunisia has at all times complied in all material respects with its obligations pursuant to Article 34 (new) of Law n°60-30 of 14 December 1960 on the organization of social security schemes, including but not limited to the declaration and payment of quarterly social contributions.
- 37.6 The Company has paid to HMRC and any other appropriate authority all Taxation, National Insurance contributions and other levies due in respect of any employee in respect of their employment by the Company.
- 37.7 The Company has obtained and maintained up to date, adequate and suitable records regarding each employee's eligibility to work in the United Kingdom (or the relevant Applicable Jurisdiction in which they are employed) in accordance with Section 8, Asylum and

Immigration Act 1996, the Immigration, Asylum and Nationality Act 2006 and/or the Immigration (Restrictions on Employment) Order 2007 (or equivalent legislation in any relevant jurisdiction).

- 37.8 All employees of the Company have a valid and subsisting permission or authority to remain in the country in which they are employed and work for the Company.
- 37.9 There is currently no employee who is a sponsored migrant under Tier 2 of the Points Based System.
- 37.10 The Company has complied with its reporting obligations in relation to any current and former employees that are sponsored migrants.
- 37.11 The Company has maintained up to date adequate and suitable records for the purposes of the Working Time Regulations and has complied with all other obligations to its workers (as "**workers**" is defined in Regulation 2, Working Time Regulations).
- 37.12 The Company has complied in all material respects with its obligations under the Agency Workers Regulations 2010 (or equivalent legislation in the relevant Applicable Jurisdiction). The Company has no reasonable grounds to believe that it is in breach of the Agency Workers Regulations 2010 and/or that any agency worker or former agency worker may bring a claim against the Company for breach of those Regulations.
- 37.13 No agreements entered into by InstaDeep SAS with third parties (including consultants or fixed-term employees) could entitle such third parties to claim for requalification of their relationship with InstaDeep SAS or any Group Company as an employment agreement as defined by French Applicable Law.
- 37.14 Neither the Company nor InstaDeep SAS is subject to any claim outstanding or threatened in writing or, so far as the Warrantors are aware, pending, in respect of working time monitoring or overtime of any employee pursuant to the French Labour Code.
- 37.15 Each Group Company has complied in all material respects with their respective obligations in respect of employee whistle-blowing policies, practices and procedures pursuant to Applicable Law, including but not limited to:
- (a) in respect of InstaDeep SAS, n° 2016-1691 of 9/12/2016 ("**Sapin 2 Act**") and its implementing Decree n° 2022-1284 of 3 October 2022 ("**Implementing Decree**"); and
 - (b) in respect of South Africa, the Protected Disclosures Act 26 of 2000.
- 37.16 The Company has complied in all material respects with its obligations under Applicable Laws concerning the health and safety of its officers, employees and workers (including but not limited to compliance with The Health Protection (Coronavirus, Restrictions) (England) Regulations 2020, the carrying out of any necessary risk assessments and introduction of any "COVID-19 secure" measures) and so far as the Warrantors are aware, there are no claims, investigations or audits pending or threatened by any officer, employee, worker or third party in respect of any accident or injury which are not fully covered by insurance.
- 37.17 InstaDeep SAS complies with, and have complied in all aspects with laws and regulations relating to the implementation of put in furlough (*activité partielle*) relating to the French Covid-19 crisis measures since March 1, 2020, until the date hereof in such a way, notably but not only, that no reimbursement could be required from any of the Group Companies in this respect.
38. **Termination of employment**
- 38.1 No officer or employee of the Company has given notice or is under notice of dismissal or will be entitled to give notice solely as a result of the provisions of this Agreement.
- 38.2 All service contracts between the Company and its officers or employees can be terminated by the Company by [***] weeks' notice or less without giving rise to a claim for damages or compensation (other than a statutory redundancy payment or statutory compensation for unfair dismissal).
- 38.3 Details of all employees who have been dismissed or who have resigned in the last [***] months, together with the reason for or an explanation of the dismissal or resignation have been Disclosed.
- 38.4 There is no agreement, arrangement, scheme or obligation (whether legal or moral) for the payment of any pensions allowances lump sums or other like benefits on retirement or on death or during periods of sickness or disablement for the benefit of any employee or former employees or for the benefit of dependants of such persons.

39. **General**

- 39.1 Details of any employee who is currently absent from work (including but not limited to those on secondments, maternity leave, paternity leave, adoption leave, shared parental leave, parental leave or absent for any other reason) or who is anticipated to be absent from work for any reason for a period of [***] month or more have been Disclosed.
- 39.2 Details of any disciplinary action (including warnings, suspension with or without pay, demotion and performance management or monitoring) taken by the Company against any employee within the previous [***] months have been Disclosed.
- 39.3 Details of any grievance made by any employee within the previous [***] months have been Disclosed.
- 39.4 The Company has not made any loan or advance to any employee which is outstanding.

40. **Industrial relations**

- 40.1 Details of any court or tribunal case, claim or action brought by any present or former officer, employee, worker or consultant within the previous [***] years and details of any court or tribunal case, any claim or action which the Warrantors have reasonable grounds to believe to the best of their knowledge, information and belief, that any such person may bring against the Company have been Disclosed.
- 40.2 So far as the Warrantors are aware, none of the provisions of this Agreement is likely to lead to any industrial trade dispute.
- 40.3 The Company has not received a request for recognition pursuant to the Trade Union and Labour Relations (Consolidation) Act 1992 nor is the Company party to any contract, agreement or arrangement with any trade union or other body or organisation representing any of its employees nor has it done any act which might be construed as recognition of a trade union.
- 40.4 The Company has in relation to its officers and employees and former officers and employees complied with all relevant legislation (including, without limitation, the TUPE Regulations and the Working Time Regulations), conditions of service, customs and practices and, where relevant, all collective agreements, recognition agreements, workforce agreements and relevant agreements for the time being.
- 40.5 There has been no recommendation made by an Employment Tribunal in relation to the Company and/or any of its employees. Any recommendations made by an Employment Tribunal have been complied with.
- 40.6 In the [***] months preceding the date of this Agreement, the Company has not given notice of any redundancies to the Secretary of State or started consultations with any appropriate representatives in respect of any employees.
- 40.7 The Company has not been a party to any relevant transfer as defined in the TUPE Regulations and no employee has been dismissed or is under notice of termination by reason of or in connection with the TUPE Regulations and the Company has not purported to vary any contract of employment where the sole or principal reason for the change is the transfer.
- 40.8 No dispute has arisen between the Company and a material number or category of its employees or workers nor are there any present circumstances known to the Warrantors which are likely to give rise to any such dispute.
- 40.9 Details of any collective agreement (whether with a trade union, staff association or any other body representing workers and whether legally binding or not) have been Disclosed.
- 40.10 No training schemes, arrangements or proposals exist nor have there been any such schemes, arrangements or proposals in the past [***] years in respect of which a levy may become payable by the Company under the Industrial Training Act 1982.
- 40.11 No investigation is in progress or, so far as the Warrantors are aware, planned to be made in respect of the Company by the Health and Safety Executive, the Equality and Human Rights Commission and/or any similar body. The Company is not and has not been subject to any enforcement order made by the Health and Safety Executive, the Equality and Human Rights Commission and/or any similar body and there is no outstanding liability to any such body for any penalty, fine or otherwise.
- 40.12 No outstanding liability has been incurred by the Company for breach of any contract of employment or redundancy payments, protective awards, compensation for wrongful dismissal or unfair dismissal or for failure to comply with any order for reinstatement or re engagement of any person or in respect of any other liability arising out of termination of any contract of employment or contract for services.

Pensions

41. Company pension schemes or other retirement benefit schemes

41.1 Save for the Pension Scheme(s), there is not in operation by the Company and there has not, at any time, been in operation by the Company (and no proposal has been announced by the Company to enter into or establish) and the Company has no liability in respect of any plan, scheme, agreement, arrangement, custom or practice (whether legally enforceable or not or whether or not approved or registered by HMRC) for the payment of (or for the payment of any contribution towards), any pensions, allowances, lump sum or other like benefits payable on retirement, death, termination of employment (whether voluntary or not or whether arising from a transfer of an undertaking within the meaning of the TUPE Regulations or otherwise) or during periods of sickness or disablement, for the benefit of any of the employees (or ex-employees) or directors (or ex-directors) of the Company or for the benefit of the dependants of any of such employees or directors of the Company.

41.2 In relation to the Pension Scheme(s) and each plan, scheme or arrangement Disclosed:

- (a) full details of all of its current and former participating employers and all employees and ex-employees who are members of it at Completion have been Disclosed;
- (b) all contributions which are payable by the Company in respect of it and all contributions due from the employees as members of it which have fallen due to be paid, and all fees, charges and expenses due have been duly paid in accordance with Applicable Law;
- (c) every person who has had a right to join, or apply to join, it has been properly advised of that right and no employee of the Company has been excluded from membership of it or from any of the benefits under it in contravention of any of its provisions, any employment contract;
- (d) it has been administered in all material respects in accordance with Applicable Law;
- (e) all benefits (other than a refund of contributions with interest where appropriate, spouses' death in service and ill health early retirement pensions) payable on the death of a member while in service, or during a period of sickness or disability of a member, are fully insured under a policy effected with an insurance company to which section 275 of the Finance Act 2004 applies and all insurance premiums due have been paid and the Warrantors are not aware of any circumstances in which such insurance would be invalidated. Each member has been covered for that insurance at the insurance company's usual rates and on its usual terms for persons in good health;
- (f) prior to 6 April 2006 it has at all times been a personal pension plan (within the meaning of Chapter IV Part XIV of ICTA), and with effect from 6 April 2006 it has been a registered pension scheme within the meaning of Chapter 2 of the Finance Act 2004, and nothing has been done or omitted to be done which will or may result in the cessation of such approval or registration;
- (g) no undertakings or assurances have been given to any of the employees of the Company as to the continuance, introduction, increase or improvement of any rights or entitlements in relation to pension, death, disability or retirement;
- (h) it provides only money purchase benefits as defined in section 181 Pension Schemes Act 1993; and
- (i) no claim or complaint has been threatened or made or litigation commenced against the Company (or its trustees, administrators or principal employer or any other person whom the Company is liable to indemnify or compensate) in respect of any matter arising out of or in connection with it and so far as the Warrantors are aware there are no circumstances which may give rise to any such claim or litigation.

42. Compliance relating to stakeholder pension schemes and auto-enrolment

The Company has complied with all its obligations relating to automatic enrolment including without limitation under the Pensions Act 2008 and regulations made thereunder.

43. General

None of the employees of the Company has been transferred to it in connection with a business transfer to which the TUPE Regulations may have applied.

The Properties

44. Title

44.1 The Properties comprise all the properties presently leased, occupied, held or otherwise used by the Company.

- 44.2 No Group Company owns any freehold property.
- 44.3 Each of the Properties is occupied or otherwise used by the Company under the Leases, the terms of which permit its occupation or use as tenant and there are no outstanding circumstances which would restrict the continued possession and enjoyment of any of the Properties or any part of them.
- 44.4 The Company has not had occasion to make any claim or complaint in relation to any neighbouring property or its use or occupation and there are no disputes, claims, actions, demands or complaints in respect of any Property which are ongoing nor so far as the Warrantors are aware anticipated and no notices materially affecting any Property have been given or received by the Company and not complied with.
45. **Encumbrances**
- 45.1 No Property is subject to any outgoing other than rent, insurance rent and service charges.
- 45.2 So far as the Warrantors are aware, no matter exists which is registered or is properly capable of registration against any Property as a Land Charge, Local Land Charge, notice or restriction.
- 45.3 Where any matter has been Disclosed against sub-paragraphs 45.1 to 45.2 45.2 (inclusive), the obligations and liabilities imposed and arising under the Disclosed matter have been observed and performed in all material respects and any payments in respect of it which are due and payable have been duly paid.
46. **Leasehold properties**
- 46.1 Each Lease is valid and in full force and there are no circumstances which would entitle any landlord or other person to exercise any power of entry or take possession of any of the Properties.
- 46.2 The Company, and each Group Company as applicable, has paid the rent and observed and performed the covenants on the part of the tenant and the conditions contained in any Lease to which it is a party.
- 46.3 All licences, consents and approvals required from the landlords and any superior landlords for the grant of the Leases and during the continuance of the Leases have been obtained and any covenants on the part of the tenant contained in those licences, consents and approvals have been duly performed and observed.
- 46.4 So far as the Warrantors are aware, there are no rent reviews outstanding or in progress under any Lease.
- 46.5 There is no obligation to reinstate any Property by removing or dismantling any alteration made to it by the Company and the Company has not incurred any liability for dilapidation.
- 46.6 The Company has not in the past [***] years been the tenant of or guarantor of any leasehold premises not listed in Schedule 3 (*The Properties*) in respect of which any obligations or liabilities could still accrue to the Company.
- 46.7 The sale of the Completion Shares will not constitute an assignment or other dealing in respect of any of the Properties under the terms of the Leases.
47. **Regulation S**
- 47.1 No Non-US FME Shareholder is a "U.S. person" (as defined in Regulation S) under the Securities Act or an underwriter or dealer within the meaning of the Securities Act.
- 47.2 Each Non-US FME Shareholder is receiving Consideration Shares and Consideration ADSs for his, her or its own account for investment and not for the benefit of any U.S. person or with a view to any resale, distribution or other disposition of the Consideration Shares or Consideration ADSs.
- 47.3 Each Non-US FME Shareholder is acquiring the Consideration Shares and Consideration ADSs in an "offshore transaction" (as defined in Regulation S).
- 47.4 None of the Non-US FME Shareholders or their affiliates (as defined in Regulation 501 under the Securities Act), nor any persons acting on their behalf has engaged in any directed selling efforts (as defined in Regulation S) with respect to the Consideration Shares and the Consideration ADSs, and it and they have complied and will comply with the offering restrictions of Regulation S.

Schedule 5
(Limitations on liability)

1. The liability of the Warrantors under the Warranties shall be reduced if and to the extent that the loss shall have been recovered under the Tax Covenant (and vice versa).
2. The Warrantors shall not be liable for any Warranty Claim if, and to the extent that, the fact, matter, circumstance or event giving rise to such Warranty Claim has been Disclosed in the Signing Disclosure Letter in respect of the Warranties given at the date of this Agreement and Disclosed pursuant to sub-clause 6.2 (*Pre Completion obligations*) or in the Completion Disclosure Letter in respect of the Warranties repeated on the Completion Date, provided that nothing in the Signing Disclosure Letter and/or the Completion Disclosure Letter shall limit the Warrantors' liability under the Tax Covenant. For the avoidance of doubt, where a disclosure in the Disclosure Documents includes any estimate, forecast or statement of opinion as to the amount of any liability, cost or expense then, provided such estimate, forecast or statement of opinion is given in good faith, the fact that the amount turns out to be inaccurate shall not of itself render the disclosure not Disclosed.
3. The Warrantors shall not be liable for a Claim unless:
 - (a) written notice from or on behalf of the Purchaser giving reasonable details of the Claim has been deemed served on the Warrantors in accordance with the provisions of clause 24 (*Notices*):
 - (i) in the case of any Non-Tax Claim, on or before the expiration of [***] years from Completion; or
 - (ii) in the case of any Tax Claim, not later than [***] years from Completion;
 - (b) the amount of the Claim:
 - (i) exceeds £[***], in which case the Warrantors shall be liable for the whole amount of the Claim and not simply the excess paid. For the purposes of this paragraph 3(b)(i), Claims arising from the same events or causes shall be regarded as a single Claim; and
 - (ii) when aggregated with all other Claims made on the same occasion or previously, is equal to or exceeds £[***] (in which case the Warrantors shall be liable for the whole amount of all of the Claims and not simply the excess).
4. The Warrantors shall not be liable in respect of any Warranty Claim arising from any matter if, on or before the date falling [***] Business Days after the day on which notice of that claim is given under paragraph 3(a) above, the Warrantors either prevented the Purchaser from suffering any losses in respect of that matter or have caused any losses so suffered by the Purchaser to be made good. The Purchaser shall comply with all reasonable requests made by the Warrantors during that period for the purposes of preventing any such losses or causing them to be made good.
5. The Warrantors shall not be liable in respect of any Warranty Claim unless legal proceedings in relation to that Warranty Claim are validly issued and served on the relevant Warrantors on or before the [***] anniversary of the last date on which notice of that Warranty Claim can be given under paragraph 3(a)(ii). For the purposes of this Agreement, legal proceedings shall be regarded as having been served when the relevant step referred to in the Civil Procedure Rule 7.5(1) has been completed.
6. Except as provided in paragraph 16 below, the aggregate liability of the Warrantors in respect of all Claims, irrespective of whether:
 - (a) the W&I Policy continues in full force and effect or not; or
 - (b) the W&I Insurer makes payment to the Purchaser in respect thereof,shall not exceed £[***] and subject to the other provisions of this Schedule 5 and the provisions of this Agreement, the parties agree that the Purchaser's sole right of recovery (if any) in excess of the cap on liability specified in this paragraph 6 of this Schedule 5 in respect of any and all Claims shall be under the W&I Policy.
7. The Warrantors shall not be liable for any Non-Tax Claim:
 - (a) to the extent that such Non-Tax Claim arises or is increased as a result of:
 - (i) any act, omission, transaction, arrangement or other event occurring at the request or with the consent of the Purchaser before Completion, or pursuant to or in compliance with any Transaction Document;

- (ii) or would have been reduced but for, the Purchaser failing to act (or to procure that the relevant Group Company acts) as it is required to under this Agreement;
 - (iii) the passing or coming into force of, or any change in, or in the interpretation, application or enforcement of, any legislation; or
 - (iv) any change in any accounting policies or practice or in the accounting reference date of any Group Company or the Purchaser;
- (b) if, and to the extent that, a liability arises or is increased as a result of any voluntary act or deliberate omission of the Purchaser (or any persons deriving title from it) or the Group after Completion done or suffered outside the ordinary course of business and other than:
- (i) pursuant to a legally binding obligation entered into by any Group Company before Completion; or
 - (ii) in order to comply with any law; or
 - (iii) at the request of or with the consent of the Warrantors;
- (c) based on a liability which is contingent only unless and until such contingent liability becomes an actual liability and is due and payable and capable of being quantified; or
- (d) if, and to the extent that, the loss in respect of which the Non-Tax Claim is made is recovered under an insurance policy of the Group in force on the date of such loss save to the extent that such recovery results in an increase in insurance premiums;
8. The Warrantors' liability in respect of any Non-Tax Claim shall be reduced by an amount equal to the amount of any specific provision or specific accrual made in the Accounts and/or the Management Accounts for the matter giving rise to that Non-Tax Claim.
9. If the Warrantors and/or the W&I Insurer make any payment to the Purchaser or the Company or any Group Company in relation to any Non-Tax Claim and the Purchaser or the Company or any Group Company subsequently receives from a third party (other than the W&I Insurer) any amount referable to, or any benefit which would not have been received but for the circumstances giving rise to, the subject matter of that Non-Tax Claim, the Purchaser shall, once it or the Company or other Group Company has received such amount or benefit, immediately pay or procure the payment to the Warrantors and/or the W&I Insurer (as appropriate) of either:
- (a) the amount of such receipt (after deducting an amount equal to the reasonable costs of the Purchaser and the Company and any member of the Group incurred in recovering such receipt and any Taxation payable on it); or if lesser;
 - (b) the amount paid by the Warrantors and/or W&I Insurer,
- together with any interest or repayment supplement paid to the Purchaser or the Company or any other Group Company in respect of it. Any payment made, or procured to be made by the Purchaser under this paragraph 9 shall be made to the Warrantors and/or the W&I Insurer in the same proportions as the amounts paid by the Warrantors and/or the W&I Insurer to the Purchaser or the Company or other Group Company.
10. In the absence of fraud or dishonesty or wilful non-disclosure on the part of any of the Warrantors, and without prejudice to the terms of clause 16 (*The W&I Policy*), if the W&I Insurer:
- (a) avoids the W&I Policy; and or
 - (b) rescinds the W&I Policy; and/or
 - (c) denies coverage pursuant to the terms of the W&I Policy; and/or
 - (d) in any way refuses to meet any claim under the W&I Policy thereby denying the Purchaser the benefit of the W&I Policy,
- then the Purchaser shall not pursue the Warrantors for any amounts that it would otherwise have been entitled to receive from the W&I Insurer pursuant to the terms of the W&I Policy.
11. Without limiting any obligations it may have at law or in equity, the Purchaser shall mitigate, and shall cause each Group Company to mitigate, any loss or liability which may give rise to a Claim.
12. Neither the Purchaser nor any Purchaser Group Company shall be entitled to recover damages or otherwise claim reimbursement or restitution in respect of damages, if and to the

extent of the amount the Purchaser or any Purchaser Group Company has already recovered in respect of the same damage or loss.

13. The Sellers shall have no liability in respect of a Claim to the extent that it is based on or comprises indirect or consequential damages (including loss of revenue, income or profits to the extent that these are indirect or consequential damages).
14. The Purchaser waives any and all claims (including for negligence) that it might otherwise have against any officer, employee, agent, adviser or consultant of the Sellers (or any holding company, any subsidiary and any subsidiary undertaking of any Seller or such companies) (i) in respect of any information that any such person has in any capacity supplied to the Purchaser in connection with the Warranties and/or the information Disclosed; or (ii) otherwise in connection with the transactions contemplated by this Agreement. The Purchaser acknowledges any claims under this Agreement may only be made directly against the Sellers, the Warrantors and/or pursuant to the terms of the W&I Policy (as applicable).
15. Except as otherwise expressly provided herein, the sole remedy against the Sellers and/or the Warrantors (as applicable) for any breach of any of the Warranties or any other provision of this Agreement shall be an action for damages for breach of contract (to the exclusion of any other remedy including those in tort or arising under statute) and the Purchaser irrevocably and unconditionally waives any right it may have to rescind or terminate this Agreement before or following Completion.
16. The aggregate liability of the Warrantors in respect of all Claims in respect of the Warranties at paragraph 18.14 to 18.17 of Schedule 4 (*Non-Tax Warranties*), only in so far as they relate to matters occurring in [***], shall be capped at £[***], provided that for this purpose the words "so far as the Warrantors are aware" shall be deemed to apply to all statements contained in those Warranties.

Schedule 6
(Tax Schedule)

Part 1

(Definitions and Interpretation)

1 Definitions and Interpretation

1.1 In this Agreement, unless the context otherwise requires, the following words have the following meanings:

"Accounts Relief" means any Relief which:

- (a) has been shown as an asset in the Completion Accounts; or
- (b) has been taken into account in computing (and so reducing or obviating) any provision for deferred Taxation which appears or which but for the availability or presumed availability of the Relief would have appeared in the Completion Accounts.

"COVID-19" means the 2019 outbreak of the novel coronavirus disease.

"CFA" means the Criminal Finances Act 2017.

"Coronavirus Support Payment" has the meaning given to it in Section 106(2) of the Finance Act 2020.

"CTA 2009" means the Corporation Tax Act 2009.

"CTA 2010" means the Corporation Tax Act 2010.

"Deemed Taxation Liability" means any Liability to Taxation falling within either limb (b) or limb (c) of that definition.

"Event" means any event, act, omission, circumstance or transaction whatsoever, including without limitation the execution and completion of this Agreement, the expiry of a period of time, any Group Company becoming or ceasing to be associated with any other person for any Tax purpose or ceasing to be, or becoming, resident in any country for any Tax purpose, the death, winding up or dissolution of any person or the incurring of any loss or expenditure.

"ITEPA" means the Income Tax (Earnings and Pensions) Act 2003.

"Liability to Taxation" means:

- (a) any liability to make a payment or increased payment of or in respect of Taxation or any liability to repay a payment received in respect of Tax [***] received by a Group Company (including by way of set-off), together with any interest and penalties in respect thereof, in each case regardless of whether the liability has been paid or discharged on or before Completion and regardless of whether such liability is chargeable or attributable directly or primarily to a Group Company or to any other person;
- (b) the Loss of any Accounts Relief; or
- (c) the use or setting off against any liability to Taxation, or against Profits earned, accrued or received, of any Purchaser's Relief in circumstances where, but for the use or setting off, any Group Company would have had a liability to Taxation in respect of which the Purchaser (ignoring the financial limitations on claims in Schedule 5 to this Agreement) would have been able to make a claim under the Tax Covenant.

"Loss" means any reduction, loss, absence, non-existence, non-availability, counteraction, nullification, disallowance, withdrawal or clawback for whatever reason (other than by way of utilisation or effluxion of time) and **"lost"** shall be construed accordingly.

"PAYE" means pay as you earn as it applies to income tax pursuant to ITEPA and the PAYE regulations referred to in it and as it applies for national insurance contribution purposes under the Social Security Contributions and Benefits Act 1992 and regulations referred to in it.

"Profits" means income, profits and gains, the value of any supply and any other consideration, value, measure or receipt used or charged for Tax purposes.

"Purchaser's Tax Group" means the Purchaser and any other company or companies that are, from time to time, treated as members of the same group as, or otherwise connected or associated in any way with, the Purchaser for any Tax purpose.

"Purchaser's Relief" means:

- (a) an Accounts Relief;

- (b) any Relief which arises to any Group Company in respect of any period after Completion or any Relief which arises in respect of any Event occurring after Completion; and/or
- (c) any Relief arising to any member of the Purchaser's Tax Group (other than a Group Company) at any time.

***]

***]

"Relief" means any relief, loss, allowance, set-off or credit for Taxation or any deduction in computing Profits for the purposes of Taxation or any right to repayment of Taxation or to a payment in respect of Taxation [***].

"Seller Associate" means any Seller and any other person with whom the Seller and/or (prior to Completion) any Group Company is or was either associated or connected for any Tax purpose.

"Tax" or **"Taxation"** means any and all forms of taxes, contributions, levies, imposts, duties or charges in the nature of Taxation and all withholdings or deductions in respect thereof of any nature whenever created or imposed and whether of the UK or any other jurisdiction, and all penalties, fines, charges, surcharges, costs and interest relating to such or which arises as a result of the failure to pay any Taxation on the due date for payment or to comply with any obligation relating to Taxation, together with the cost of removing any related charge or other encumbrance.

"Tax Assessment" means any notice, demand, assessment, self-assessment, letter or other document issued or action taken by or on behalf of any Tax Authority or any person (including any Group Company) indicating that any person is or may be placed or sought to be placed under a Liability to Taxation for any pre-Completion period (or any other liability under the Tax Covenant or in respect of which the Warrantors may be liable for breach of the Tax Warranties).

"Tax Authority" means any taxing or other authority, body or official competent to administer, impose, assess or collect any Taxation in the UK or elsewhere.

"Tax Claim" means a claim by the Purchaser against the Warrantors under the Tax Covenant or for breach of any of the Tax Warranties.

"VAT" means value added tax in the UK or equivalent Tax in any other jurisdiction and references to VAT shall include all law relating to value added tax in the UK and any value added, turnover, sales, purchase or similar Tax of any other jurisdiction and references to value added tax shall be construed accordingly.

1.2 In this Schedule:

- (a) references to Profits earned, accrued or received shall include any Profits which are for the purpose of any Tax treated or regarded as earned, accrued or received;
- (b) references to Profits earned, accrued, or received on or before a particular time (including, without limitation, Completion) or in respect of a particular period shall include Profits which are for the purposes of any Tax treated as earned or accrued, arising or received on or before that time or in respect of that period;
- (c) references to social security contributions shall also include references to national insurance contributions (and vice versa), and reference to either shall include apprenticeship levy or any similar Tax;
- (d) references to any law shall include any statute, statutory instrument, law, regulation, treaty, notice, directive or similar provision relating to Taxation, whether of the UK or elsewhere;
- (e) references to specific parts of the law of the UK shall be taken to include a reference to the law of any other jurisdiction so far as the same may apply to any Group Company and may be similar to or have a similar purpose or which most closely approximates to the law of the UK to which reference is made;
- (f) references to the occurrence of Events on or before a particular date (including, without limitation, Completion) or in respect of a particular period shall include Events which are for the purposes of any Tax treated as having occurred or existed at or before that date or in respect of that period;
- (g) references to a repayment of Tax shall include any repayment supplement or interest in respect of it;

- (h) any stamp duty charged on any document (or in the case of a document that is outside the UK, any stamp duty that would be charged on the document if it were brought into the UK) that is necessary to establish the title of any Group Company to any asset, and any interest, fine or penalty relating to the stamp duty, shall be deemed to be a liability of the relevant Group Company to make an actual payment of Tax because of an Event arising on the date of execution of the relevant document (and for the avoidance of doubt the payment of any stamp duty on any document, or the bringing into the UK of any document, shall not be considered a voluntary act for the purposes of paragraph 1(d) of Part 4 of this Schedule); and
 - (i) references to the **due date for payment** of any Tax shall be read and construed as a reference to the last day on which such Tax may by law be paid without incurring a penalty or liability for any interest, charge, surcharge, penalty, fine or other similar imposition accruing or without a surcharge liability notice being liable to be issued (after taking into account any postponement of such date which is obtained for such Tax).
- 1.3 It shall be assumed for all of the purposes of this Tax Schedule (and in particular for calculating any liability to Taxation or any Relief) that the date of Completion is the end of an accounting period for the purposes of any relevant Tax and all such adjustments and apportionments as may be required consequent on such assumption shall be made in assessing any liability or in making any calculation required under this Schedule.
- 1.4 Any payments made by the Warrantors pursuant to or under or in respect of the Tax Covenant or for breach of any Warranty shall, so far as possible, be treated as an adjustment to the consideration paid by the Purchaser for the Shares (and so far as is possible, a reduction pro-rata of such consideration) provided always that this paragraph shall not operate in any way to limit the liability of the Warrantors under this Schedule or the Agreement or otherwise.
- 1.5 Any covenant, indemnity or other requirement to pay costs and/or expenses in this Agreement (including by way of deduction of such costs and/or expenses from any payment due to another party) shall be treated as excluding any VAT on such costs and/or expenses to the extent that the party incurring such costs is able to obtain an input tax credit in respect of such VAT.

Part 2
(Tax Warranties)

1. Tax Warranties

- 1.1 Each Group Company has paid all Taxation for which it is liable and made all withholdings and deductions in respect, or on account, of any Taxation from any payments made by it which it is obliged to make and has paid to the appropriate Tax Authority all amounts so withheld or deducted by the due date for payment.
- 1.2 Each Group Company has in the last [***] years (or in respect of any earlier period in respect of which any relevant Tax return is open for reassessment by any Tax Authority) prepared and submitted within applicable time limits all notices, returns accounts, computations, statements, assessments, claims, disclaimers, elections and applications for clearances or consents required for Tax purposes and provided complete and accurate information to any Tax Authority.
- 1.3 Each Group Company has kept and maintained complete and accurate records, invoices and other documents and information of whatever nature required by law to be kept for Tax purposes and has sufficient such records, invoices and other documents and information relating to past Events to calculate its liability to Taxation up to Completion and any Relief which has arisen on any disposal or realisation of any assets before Completion.
- 1.4 No Group Company is currently involved in a dispute with, or has any unsettled or outstanding assessments from, or is appealing to or against any Tax Authority in respect of Taxation and no Group Company has, within the last [***] years, been subject to any non-routine enquiry, audit, visit, inspection or other dispute with any Tax Authority and, so far as the Warrantors are aware, there are no circumstances which could give rise to a material risk of any such enquiry, audit, visit, inspection or dispute.
- 1.5 No Group Company has, within the last [***] years, been liable to pay any material sum in respect of interest, penalty, or fine in respect of Taxation.
- 1.6 No amount of Tax chargeable on any Group Company or subject to withholding or deduction by any Group Company during any accounting period ending on or within the last [***] years has to any material extent depended on any concession, agreement or, dispensation with any Tax Authority (other than in accordance with the generally applicable published guidance of such Tax Authority).
- 1.7 No circumstances exist under which any of the Shares or assets of any Group Company could be subject to any charge or other Encumbrance in respect of Taxation.
- 1.8 The Accounts make proper provision or reserve in accordance with applicable generally accepted accounting principles for Tax in respect of which each Group Company was liable on the Accounts Date and proper provision has been made in the Accounts in accordance with such accounting principles for deferred tax.
- 1.9 Since the Accounts Date:
 - (a) no Group Company has entered into any obligation to make any payment of an income or revenue nature after Completion outside the ordinary course of its business and exceeding £[***] in aggregate which, or to provide a benefit the cost of which, will be prevented from being deductible for Tax purposes, whether as a deduction in computing the profits of a trade or as an expense of management or as a charge on income or otherwise; and
 - (b) no Group Company has been a party to any Event for which any Tax clearance provided for by statute has been, or could have been, obtained.
- 1.10 No Company is, nor has at any time within the last [***] years been, a close company within the meaning of section 439 CTA 2010 and has no outstanding loans which have given rise to any liability under Chapter 3 or 3A, Part 10, CTA 2010 (loans to participators).
- 1.11 No distribution has been made or deemed to have been made by any Group Company for Tax purposes other than dividends shown in the audited accounts of the relevant Group Company.
- 1.12 No Group Company has been a member of a group for any Tax purpose with any other company other than another Group Company.
- 1.13 Neither the execution nor completion of this Agreement, nor any other event since the Accounts Date, will result in the clawback or disallowance of any relief or allowance previously given.

- 1.14 No shares or securities have been issued by any Group Company, and no options have been granted or issued in respect of such shares or securities, such that any Group Company will or may be liable to account for income tax under the PAYE system or to collect or pay any national insurance contributions including without limitation on any payment made under this Agreement.
- 1.15 There have been no arrangements that have given rise to any liability of a Group Company to account for income tax or social security contributions as a result of the application of Part 7A ITEPA and, so far as the Warrantors are aware, there are no arrangements in place that could give rise to any such liability.
- 1.16 No Group Company is or may be liable to deduct and/or account for income tax or social security contributions in respect of any persons directly or indirectly engaged otherwise than as employees of any Group Company (including through any personal service company or any managed service company).
- 1.17 Each Group Company:
- (a) is registered for the purpose of, and has complied in all respects with, the Applicable Law in respect of VAT and is not subject to any conditions (including any requirement to provide security) imposed or agreed with any Tax Authority; and
 - (b) is not, and has not within the last [***] years been, a member of a group for VAT purposes.
- 1.18 All transactions or arrangements made by each Group Company have been made on arm's length terms or with parties that were unrelated to the Group Company and the processes by which prices and terms have been arrived at have, where relevant for Tax purposes, been documented in accordance (where relevant) with all applicable transfer pricing rules. No notice, enquiry or adjustment has been made by any Tax Authority in connection with any such transactions or arrangement. The Disclosure Letter contains full details of any advance pricing agreements entered into by any Group Company with a Tax Authority.
- 1.19 No Group Company has, within the last [***] years:
- (a) entered into, or been party to, any arrangement the main purpose or one of the main purposes of which was to avoid Taxation or to obtain a Tax advantage; or
 - (b) entered into any arrangements which need to be disclosed to a Tax Authority under any legislation relating to tax avoidance.
- 1.20 No Event has occurred in the last [***] years in consequence of which any Group Company has incurred a Liability to Taxation primarily chargeable against some other person (other than another Group Company) and no Group Company is otherwise liable to be assessed to Tax as agent for, or on account of, or otherwise on behalf of, any other person.
- 1.21 Any document that may be necessary in proving the title of any Group Company to any asset which is owned by the relevant Group Company at the date of this Agreement, is duly stamped for stamp duty purposes or has had any applicable transfer or registration Tax due in respect of it paid.
- 1.22 No Group Company would be treated as land rich for the purposes of any transfer tax according to Section 726 of the French tax code.
- 1.23 Each Group Company has at all times been resident for Tax purposes in its jurisdiction of incorporation and has had no permanent establishment in any other jurisdiction and has not during the past [***] years paid or been registered for, nor been liable to pay or be registered for, Tax in any other jurisdiction.
- 1.24 So far as the Warrantors are aware, no person acting in the capacity of an associated person (as defined in section 44(4) CFA) of any Group Company has committed:
- (a) a UK tax evasion facilitation offence under section 45(5), CFA; or
 - (b) a foreign tax evasion facilitation offence under section 46(6), CFA.
- 1.25 Each Group Company has in place (and has had in place at all times since [***]) such prevention procedures (as defined in sections 45(3) and 46(4) CFA) as, so far as the Warrantors are aware, are proportionate to its business risk and are in line with any guidance published from time to time pursuant to section 47 CFA.
- 1.26 No employee or officer of any Group Company has been required to carry out their duties in a jurisdiction other than their usual jurisdiction of residence, or other than the jurisdiction in which they typically carry out their duties, for a material length of time as a result of COVID-19 related travel restrictions.
- 1.27 No Group Company has received any Coronavirus Support Payment.

Part 3
(Covenants to and from the Purchaser)

1. Tax Covenant

- 1.1 Subject to the provisions of Part 4 of this Schedule the Warrantors jointly and severally covenant to pay to the Purchaser an amount equal to:
- (a) any Liability to Taxation of any Group Company arising:
 - (i) from any Event occurring on or before Completion; or
 - (ii) in respect of, or by reference to, any Profits earned, accrued or received on or before Completion;
 - (b) any Deemed Taxation Liability;
 - (c) any Liability to Taxation of any Group Company which would not have arisen but for the failure of any person who is or has been a Seller Associate (other than a member of the Purchaser's Tax Group) to discharge a Liability to Taxation which falls upon such Seller Associate:
 - (i) arising directly or indirectly from any Event occurring or deemed to have occurred at any time by such Seller Associate; or
 - (ii) in respect of any profits earned, accrued or received at any time by such Seller Associate;
 - (d) any Liability to Taxation which is a liability of any Group Company or any member of the Purchaser's Tax Group to account for income tax or national insurance contributions, whether arising before, on or after Completion, in respect of the grant, exercise, surrender, exchange or other disposal of an option or other right to acquire securities, or in respect of any acquisition, holding, variation or disposal of, or any other Event occurring in relation to, employment-related securities (as defined for the purposes of Part 7, ITEPA) where the acquisition of the security or the grant of the option, or other right to acquire the security occurred on or before Completion;
 - (e) any Liability to Taxation under Part 7A, ITEPA which is a liability of any Group Company or any member of the Purchaser's Tax Group, whether arising before, on or after Completion, including any liability arising as a consequence of any payments or loans made to, any assets made available or transferred to, or any assets earmarked (however informally) for the benefit of any employee or former employee of any Group Company, or for the benefit of any relevant person, by an employee benefit trust or another third party where the arrangement giving rise to the charge was entered into at a time when the third party was acting on the instructions of, or for the benefit of, a Seller Associate;
 - (f) any Liability to Taxation which is a liability of the Purchaser or any Group Company or any member of the Purchaser's Tax Group to account for income tax or social security contributions arising as a result of the sale of the Shares, or the payment of (or obligation to pay), any part of the Consideration, or any agreement (whether formal or otherwise) between any of the Sellers or between any of the Sellers and any other person or persons in respect of the Consideration payable pursuant to this Agreement;
 - (g) any Liability to Taxation arising due to a failure after Completion by any employee to make good to any Group Company (or any member of the Purchaser's Tax Group) any income tax or social security contributions for which any Group Company (or any member of the Purchaser's Tax Group) is required to account in respect of any notional payment as defined in section 222, ITEPA and arising in respect of any shares, options, rights, interests or arrangements referred to in sub-paragraph 1.1(d) or in respect of any payments, loans or assets referred to in sub-paragraph 1.1(e) or 1.1(f) above;
 - (h) any Liability to Taxation being a liability for inheritance tax which:
 - (i) is a liability of any Group Company which arises as a result of a transfer of value occurring or being deemed to occur on or before Completion (whether or not in conjunction with the death of any person whensoever occurring);
 - (ii) has given rise before or on Completion to a charge on any of the shares in or assets of any Group Company or a power to sell, mortgage or charge any of the shares in or assets of the relevant Group Company; or
 - (iii) gives rise at any time after Completion to a charge on or to a power to sell, mortgage or charge any of the shares in or assets of any Group Company as

a result of the death of any person within [***] years of a transfer of value which occurred before Completion,

and in determining for the purposes of this sub-paragraph 1.1(h) whether a charge on or power to sell, mortgage or charge any of the shares in or assets of the relevant Group Company exists at any time, the fact that the inheritance tax is not yet payable, or may be paid by instalments, shall be disregarded and such inheritance tax shall be treated as becoming due, and a charge or power to sell, mortgage or charge as arising, on the date of the transfer of value or other date or event on or in respect of which it becomes payable or arises, and the provisions of section 213, Inheritance Tax Act 1984 shall not apply;

- (i) any liability to Taxation of any Group Company arising where any Group Company is not entitled (either wholly or partially) to, or is required to repay, any Coronavirus Support Payment claimed on or before Completion;
- (j) any liability of any Group Company to make a payment or repayment under any indemnity, covenant, warranty, mortgage, guarantee or charge entered into or created on or before Completion of a sum equivalent to or by reference to another person's liability to Taxation; and
- (k) any Liability to Taxation of any Group Company arising in relation to any claims for [***] submitted to any Tax Authority prior to Completion,

together with all costs and expenses reasonably and properly incurred by any Group Company or any member of the Purchaser's Tax Group in connection with the Liability to Taxation or other liability (including any related Tax Assessment) which is the subject of a successful claim under sub-paragraph 1.1 above or in taking or defending any successful action under this Schedule.

Date for payment

1.2 Where the Warrantors become liable to make any payment under this Schedule or for breach of the Tax Warranties, the due date for the making of that payment (which shall be in cleared funds) shall be the later of [***] Business Days following a written demand from the Purchaser to the FME Shareholders' Representative and:

- (a) in a case that involves an actual payment of or in respect of Taxation, the date falling [***] Business Days before the due date for payment;
- (b) in a case that involves the loss of a Relief (other than a right to repayment of or in respect of Taxation, [***]), the date falling [***] Business Days before the due date for payment of the Taxation which is payable as a result of such Loss of Relief (on the assumption that the relevant Group Company would have been able to utilise fully the Relief in the accounting period during which the Relief was lost);
- (c) in a case that involves the loss of a right to repayment of, or in respect of, Tax [***], the earliest date that the repayment (or payment) would have been made by the relevant Tax Authority (whether by actual repayment (or payment), credit or set-off);
- (d) in a case that falls within sub-paragraph (c) of the definition of Liability to Taxation, the date on which the Taxation saved (in consequence of the use or setting-off) would otherwise have become payable to the relevant Tax Authority; and
- (e) in any other case (including costs and expenses incurred under sub-paragraph 1.1) which is not covered by the preceding paragraphs, [***] Business Days following a written demand from the Purchaser to the FME Shareholders' Representative.

Amount of Liability to Taxation

1.3 The amount of any liability under sub-paragraph 1.1 of this Tax Covenant shall be:

- (a) in the case of a liability under sub-paragraph (a) of the definition of Liability to Taxation, the amount of the payment so made;
- (b) in the case of a liability under sub-paragraph (b) of the definition of Liability to Taxation:
 - (i) if the Accounts Relief is a right to repayment of or in respect of Taxation [***], the amount of the repayment or payment (as the case may be) that is Lost;
 - (ii) in any other case, the amount of Taxation that would have been saved but for the Loss of the Accounts Relief on the assumption that the relevant Group Company would have been able to fully utilise the Accounts Relief in the accounting period during which the Accounts Relief was lost; and

- (c) in the case of a liability under sub-paragraph (c) of the definition of Liability to Taxation, the amount of Taxation that has been saved in consequence of the use or setting off.

Grossing up

- 1.4 All sums payable under this Agreement (including, but not limited to, the Tax Covenant) shall be paid in full, without any set-off, counterclaim, deduction or withholding in respect of Taxation (other than any deduction or withholding required by law).
- 1.5 If any deductions or withholdings are required by law to be made from any of the sums payable by any Warrantor under this Agreement, the relevant Warrantor making the deduction or withholding shall provide any evidence of the relevant withholding as the Purchaser may reasonably require and shall pay to the Purchaser such additional amount as shall ensure that the net amount received by the Purchaser will equal the full amount that would have been received had no such deduction or withholding been required to be made.
- 1.6 If any sum payable by any Warrantor to the Purchaser under this Agreement (including, but not limited to, the Tax Covenant) is subject to Taxation in the hands of the Purchaser the amount to be paid to the Purchaser by the Warrantors making that payment shall be increased by such additional amount as will ensure that the net amount received by the Purchaser after such Taxation has been taken into account is equal to the full amount which would be receivable by the Purchaser had the amount not been subject to Taxation.
- 1.7 The provisions of sub-paragraphs 1.5 and 1.6 shall not apply if and to the extent that:
 - (a) the amount payable in respect of or in connection with the Claim or other obligation giving rise to the payment includes an amount in respect of or otherwise taken into account such Taxation; and
 - (b) the Purchaser (including any other recipient of the payment) is at any time resident for Tax purposes in a jurisdiction other than Germany and the amount payable (if any) pursuant to or in consequence of sub-paragraphs 1.5 and 1.6 would have been less had the Purchaser (or other recipient) been at all times so resident only in Germany.
- 1.8 Purchaser shall be entitled to deduct any income tax or social security contributions, other than employer social security contributions, from any payments of Consideration to the extent it or any Group Company is obliged to account for such Taxes in respect of any payment of Consideration and the making of such deduction is not prohibited as a matter of law. The Purchaser shall consult in good faith with the FME Shareholders' Representative prior to seeking any ruling or guidance from any Tax Authority as to whether there is or will be such an obligation and if the Purchaser considers that it is or may be obliged to account for any such Taxes it shall in good faith consult with the FME Shareholders' Representative Sellers prior to any making any such deduction.

Part 4
(Limitations and general)

1. Limitations on liability

1.1 The Warrantors shall not be liable under the covenant contained in sub-paragraph 1.1 of Part 3 of this Schedule or for breach of the Tax Warranties if and to the extent that:

- (a) allowance, provision or reserve in respect of the liability in question was made in the Completion Accounts;
- (b) payment or discharge of the liability in question was taken into account in calculating the net assets of the Company in the preparation of the Completion Accounts;
- (c) the liability in question arises or is increased as a result of:
 - (i) any increase in rates of Taxation;
 - (ii) any change in law or in the judicial interpretation of the law or in the published practice of any Tax Authority (other than a change targeted specifically at counteracting any tax avoidance scheme);
 - (iii) any change in accounting practice or principles or any change in the bases on which the accounts of the relevant Group Company are prepared except, in either case, in order to comply with generally accepted accounting principles to the extent applicable to the relevant Group Company immediately before Completion; or
 - (iv) any change in the date to which the relevant Group Company makes up its accounts, announced and coming in to force in any such case after Completion (provided that this paragraph (c) will not apply to a liability under sub-paragraph 1(f) and any related liability under 1.1(g) or any payment made under sub-paragraphs 1.5 or 1.6);
- (d) the liability in question would not have arisen but for a voluntary act carried out or effected by the Purchaser or any member of the Purchaser's Tax Group at any time or by the relevant Group Company at any time after Completion which the Purchaser knew or ought reasonably to have known would give rise to the liability in question, other than any act carried out or effected:
 - (i) under a legally binding commitment created on or before Completion;
 - (ii) in order to comply with any law as it was immediately prior to Completion;
 - (iii) in the ordinary course of the business of that Group Company as carried on immediately prior to Completion;
 - (iv) in order to mitigate any penalty or interest (including without limitation, making a voluntary disclosure to any Tax Authority);
 - (v) at the written request of the FME Shareholders' Representative; or
 - (vi) pursuant to the Agreement;
- (e) the liability in question would not have arisen or been increased or would have been reduced or eliminated but for a failure or omission on the part of any Group Company after Completion to make any valid claim, election, surrender, or disclaimer or to give any valid notice or consent in circumstances where the making, giving or doing of which was taken into account in computing the allowance, provision or reserve for Taxation in the Completion Accounts but only to the extent that the Purchaser was aware or ought reasonably to have been aware by the due date for making the relevant claim, election, surrender, disclaimer, notice or consent that the relevant claim, election, surrender, disclaimer, notice or consent was so taken into account;
- (f) there is available to any Group Company (at no cost to any Group Company or any member of the Purchaser's Tax Group) to relieve or mitigate the liability in question any Relief which is not a Purchaser's Relief and for these purposes it shall be assumed that any Group Company has made all such claims and elections required for such Relief to be so available; or
- (g) the Purchaser or the relevant Group Company has already been compensated in respect of the liability in question under any other provision of this Agreement.

2. Claims

On the Purchaser or any Group Company becoming aware of a Tax Assessment, the Purchaser shall, or shall procure that the relevant Group Company shall as soon as

reasonably practicable give written notice of that Tax Assessment to the FME Shareholders' Representative and shall procure that the FME Shareholders' Representative is promptly provided with copies of any correspondence with the Tax Authority and kept fully informed of any actual or proposed material developments (including meetings with a Tax Authority) relating to the Tax Assessment. This paragraph shall not apply where the provisions of clauses 4.9 to 4.12 apply.

3. **Tax Returns**

3.1 The Purchaser shall (or shall procure that the relevant Group Company shall):

- (a) keep the FME Shareholders' Representative informed of all material matters relating to the submission, negotiation and agreement of the corporation tax returns and computations of each Group Company for all accounting periods ended on or prior to Completion and the pre-Completion part of the accounting period current at Completion (the "**Relevant Accounting Periods**"); and
- (b) ensure that no such computations or returns nor any material correspondence relating to such computations or returns for the Relevant Accounting Periods shall be transmitted to any Tax Authority without giving the FME Shareholders' Representative a reasonable opportunity to make representations thereon and the Purchaser shall take into account such representations and shall not unreasonably refuse to incorporate any reasonable comments of the FME Shareholders' Representative that are provided to the Purchaser in writing and on a timely basis.

3.2 The Warrantors shall provide the Purchaser and each Group Company with all reasonable assistance, co-operation and information in relation to the preparation and agreement of the tax returns for Relevant Accounting Periods and any matter arising therefrom.

3.3 Where any matter relates to a Tax Assessment which is likely to or may give rise to a liability under this Schedule or in respect of the Tax Warranties (ignoring the financial limitations on claims in Schedule 5 to this Agreement), the provisions of the W&I Policy (including the conduct of claims provisions set-out therein) shall take precedence over the provisions of paragraph 3.1(b) and nothing in this paragraph 3 shall oblige the Purchaser to do anything which would lead to a breach of, or which would otherwise prejudice or adversely impact its rights under, the W&I Policy.

4. **Warrantors' Access to information**

The Purchaser shall procure that all material books and records of each Group Company relating to the period prior to Completion are preserved for [***] years following Completion and are retained in the jurisdiction of incorporation of the relevant Group Company. The Purchaser shall make available to any Warrantor any such books and records of the relevant Group Company (or, if practicable, the relevant parts of such books and records) which are reasonably required by that Warrantor for the purpose of dealing with its or his Tax affairs and, accordingly, the Purchaser shall, upon being given reasonable notice by any Warrantor and subject to that Warrantor giving such undertaking as to confidentiality as the Purchaser shall reasonably require, procure that such books and records are made available to that Warrantor for inspection (during normal working hours) and copying for and only to the extent necessary for such purpose.

Schedule 7
(Completion obligations)
Part 1
(Sellers' obligations)

1. On Completion:
- 1.1 Each Seller shall deliver (or procure the delivery of) to the Purchaser:
 - (a) stock transfer forms, duly completed and executed by the registered holders, in favour of the Purchaser (or as it may direct) in respect of the Completion Shares together with the relevant share certificate(s) (or, where such certificate(s) have been lost or destroyed, an indemnity in a form satisfactory to the Purchaser in respect of such certificate(s));
 - (b) in so far as that Seller (other than the Founder Sellers) has the right to nominate directors of a Group Company, letters of resignation in a form to be agreed between the applicable Seller and the Purchaser acting reasonably, from each of the directors and the company secretary (as applicable) of each Group Company that such Seller nominated;
 - (c) a copy of each power of attorney under which any document to be delivered to the Purchaser by it on Completion has been executed;
 - (d) the Option Exercise Documents duly executed by the parties thereto; and
 - (e) a Deed of Adherence in respect of each New FME Shareholders, duly executed by the New FME Shareholder (or by a duly authorised attorney).
- 1.2 Each Non-US FME Shareholder shall deliver (or procure the delivery of) to the Purchaser (to the extent not provided prior to Completion), a duly executed Non-US FME Shareholders' ADS Letter of Representation.
- 1.3 The Founder Sellers shall deliver (or procure the delivery of) to the Purchaser (to the extent not provided prior to Completion):
 - (a) the Companies House webfiling authentication code for the Company;
 - (b) unless they are kept at a Property or held physically or electronically by a third party that is engaged by a Group Company, all cheque books, credit and charge cards held for the account of each Group Company;
 - (c) to the extent notified to the Founder Sellers by the Purchaser no later than [***] Business Days in advance of Completion, letters of resignation, in a form to be agreed between the Founder Sellers and the Purchaser acting reasonably, each of the persons and in respect of those positions held in one or more Group Companies, as is/are specified in such notice;
 - (d) letters of resignation, in a form to be agreed between the Founder Sellers and the Purchaser acting reasonably, from the auditors of each Group Company containing the statement specified in Section 519, CA2006 (or the equivalent legislation in each relevant jurisdiction);
 - (e) the New Articles of Association;
 - (f) the Completion Disclosure Letter duly signed (if applicable);
 - (g) the Confirmatory IP Assignments, duly executed;
 - (h) evidence satisfactory to the Purchaser that each Minority Share Transfer has been completed in accordance with all Applicable Law and is in full force and effect;
 - (i) an amended service agreement between the Company and [***] including (i) a provision whereby no commissions are due to by the Company [***] with effect from Completion; and (ii) any other changes as may be agreed between [***] and the Company between the date of this Agreement and Completion, such amended service agreement duly signed by [***] and the Company, to take effect from Completion;
 - (j) to the extent the terms of a service agreement between [***] and the Company (or any other Group Company) is agreed between the date of this Agreement and Completion, such service agreement (in a form to be agreed between [***] and the Purchaser acting reasonably) duly signed by [***] and the Company (or any other respective Group Company), to take effect from Completion;

- (k) the Post-Completion Management Agreement, duly signed by the Founder Sellers and the Company;
 - (l) a copy of each power of attorney under which any document to be delivered to the Purchaser by a Seller Founder on Completion has been executed;
 - (m) copies of any shareholder and/or director resolution of any Group Company for which it is required in connection to Completion, together with copies of all other consents or approvals (if any) referred to in such resolutions;
 - (n) all elections by the Optionholders taken under Section 431(1), ITEPA, duly executed; and
 - (o) board resolution of the Company in the Dubai Digital Authority's prescribed format approving the resignation of the general manager of the InstaDeep Dubai branch and a board resolution of the Company in the ADGM prescribed format approving the resignation of the authorised signatory of the InstaDeep Abu Dhabi branch and the appointment of the relevant replacements as directed by the Purchaser for these branches. Such resolutions must be legalised, notarised and attested up to UAE embassy level in the UK, as applicable.
- 1.4 The Sellers' Representatives shall:
- (a) deliver the Paying Agent Agreements, duly signed by them and the Company; and
 - (b) deliver to [***] a duly signed counterpart of the Payment Notice in respect of the Initial Disbursement Amount (as each term is defined in the Paying Agent Agreement for paying agency services).
- 1.5 The Sellers shall procure, in so far as it is in their respective power as shareholders of the Company to do so, that a duly convened and quorate board and/or shareholder meeting (or equivalent written resolution) of any Group Company for which the Purchaser and the FME Shareholders' Representative agree is required, is held at which (to the extent relevant):
- (a) the stock transfer forms referred to in sub-paragraph 1.1(a) are approved and (subject to them being appropriately stamped) registered in the Company's books;
 - (b) such director and/or general manager and/or authorised signatories and/or secretary of a Group Company as have been notified by the Purchaser in advance of Completion cease to be an officer of the relevant Group Company with immediate effect;
 - (c) the persons nominated by the Purchaser are appointed as director and/or general manager and/or authorised signatory and/or the secretary (as applicable) of any relevant Group Company;
 - (d) any service agreements referred to in sub-paragraph 1.3(i) and 1.3(j) are approved;
 - (e) the mandates given by each Group Company to its bankers are revoked or revised as the Purchaser may require; and
 - (f) the execution and completion of the other documents to be entered into by each Group Company under this Agreement is approved as appropriate.

Part 2

(Purchaser's obligations)

- 1.1 On Completion, the Purchaser shall deliver (or procure the delivery of) to the Sellers (to the extent not provided prior to Completion):
- (a) the Post-Completion Management Agreement, duly signed by the Purchaser; and
 - (b) the Paying Agent Agreements, duly signed by the Purchaser.

Schedule 8

(Pre Completion obligations)

1. Between the date of this Agreement and Completion each Seller shall, in so far as it is in its power to do so as a shareholder of the Company, procure that (save with the prior written consent of the Purchaser):
 - (a) the Group shall carry on business in the normal and ordinary course;
 - (b) reasonable advance notice is given to the Purchaser of any meeting of the board of directors of each Group Company (together with an agenda of the business to be transacted at such meeting and all supporting documents) and that a duly authorised representative of the Purchaser is permitted to attend as an observer at such meeting;
 - (c) each Group Company does not conduct its affairs in a manner which could reasonably be considered as damaging or otherwise prejudicial to the goodwill of the Group or its relationship with its customers, suppliers or employees and that no adverse representations about the Purchaser are made by any Group Company or any of its employees, directly or indirectly to any third parties who are suppliers to or customers of the Group or otherwise;
 - (d) no Group Company shall, save in the normal and ordinary course of business:
 - (i) lend any monies, other than advances (i) to any Group Company; or (ii) by way of deposit with a bank or other financial institution whose normal business includes the acceptance of deposits; or (iii) to any individual employee for the purposes contemplated by and in accordance with that employee's terms of employment;
 - (ii) borrow any monies or otherwise create any indebtedness except in relation to the operation of bank overdrafts within existing limits or term loan from its bankers not exceeding £[***] as required in the ordinary course of business or otherwise amend the terms of any indebtedness;
 - (iii) give or allow to exist any further Encumbrance over any of its assets or undertaking;
 - (iv) enter into capital expenditure commitments, hire purchase, leasing, rental or conditional sale agreements or arrangements for an aggregate amount in excess of £[***];
 - (v) enter into any agreement or arrangement which is outside the ordinary course of its business or not capable, in accordance with its terms, of being performed in full within twelve months of the date on which it is entered into or incurred or which cannot be terminated by the relevant Group Company by giving notice or where more than [***] months need to lapse before the relevant Group Company can terminate;
 - (vi) declare, make or pay any dividend or other distribution or allot, issue, grant any options over, redeem, purchase, consolidate, convert, reclassify, sub-divide or reduce or otherwise reorganise or change any share or loan capital or issue any share warrants or securities convertible into shares, except for granting New Awards (provided that the New Awards will not cause the number of Completion Fully-Diluted Shares to exceed [***]);
 - (vii) sell, transfer or otherwise dispose of the whole or any part of its business, undertakings or assets or otherwise make any change to its business structure or organisation;
 - (viii) give any financial or other guarantees, securities or indemnities for any purpose;
 - (ix) commence any litigation or compromise or settle any claim, dispute or other matter in which it is involved which has a claim value in excess of £[***], except for debt collection in the ordinary course of business;
 - (x) change its auditors or its accounting reference date;
 - (xi) register the transfer of any of the Shares;
 - (xii) cancel, compromise, waive or release any debt of the Company or any Group Company in excess of £[***];
 - (xiii) attempt to do any of the matters set out in sub-paragraphs (d)(i) to (x) (inclusive); or

- (xiv) increase any fees, earnings, remuneration or benefits paid or payable to any officer, employee, consultant or worker of a Group Company by more than [***]%;
 - (e) no additional directors shall be appointed to the board of directors of any Group Company;
 - (f) no resolution is passed by the shareholders of any Group Company;
 - (g) there shall be no material change in the terms and conditions of employment of any Senior Employee of any Group Company or of the terms of engagement of any contractor engaged by any Group Company for services with annual cost to the Company of £[***] or more and no Senior Employee's employment with any Group Company shall be terminated by such Group Company or new Senior Employees engaged by such Group Company;
 - (h) the Group maintains in force all insurance policies that are in force on the date of this Agreement; and
 - (i) each Group Company pays its creditors in the ordinary course of its business or within the normal terms of payment of such creditors.
2. Any Group Company may take all or any of the following actions without breach by the Sellers of paragraph 1, provided the Sellers' Representatives notify the Purchaser and, where timing is not of the essence, allow the Purchaser the opportunity to provide its views and comments on the proposed actions:
- (a) any action required to be taken in order to comply with any applicable law or regulation (including any action taken by any director of a Group Company to ensure compliance with his duties as a director);
 - (b) the completion or performance of any obligations pursuant to any contract or arrangement entered into before the date of this Agreement;
 - (c) anything required to be done in order to effect the terms of this Agreement or any action taken at the request of the Purchaser and to which the Seller has agreed; and
 - (d) any action reasonably taken in response to events (a) beyond the control of the Group Companies or any Seller; or (b) within the control of the Group Companies or of any Seller, but which require urgent response; in each case to the extent taken with the intention of minimising the adverse effect of those events on the business of the Group Companies or any member of the Seller Group.

Schedule 9
(Completion Accounts)

Part 1

(Preparation)

1. For the purposes of this Schedule 9, notification to and/or by the Sellers shall be satisfied by notification (in accordance with the relevant paragraph of this Schedule 9) to or by the Sellers' Representatives.
2. The Purchaser shall within [***] Business Days of Completion, prepare and deliver to the Sellers:
 - (a) a draft income statement of the Group in respect of the period from [***] to the Effective Time; and
 - (b) a draft balance sheet of the Group as at the Effective Time,(such income statement and balance sheet being the "**draft Completion Accounts**"); and
 - (c) the Purchaser's calculation of the Actual Adjustment Statement based on the draft Completion Accounts.
3. The Founder Sellers shall procure (so far as it lies within their powers) that the Purchaser and the Purchaser's advisers and representatives shall be given full access (during normal business hours after having given reasonable advance notice provided that no such access shall unreasonably interfere with the normal business operations of the Purchaser or the Group) to the Group's accounts and records and shall be permitted to take copies of the same and generally be provided with such other information and assistance as they may reasonably require to prepare such draft Completion Accounts and in a timely fashion.
4. The Purchaser shall procure that the draft Completion Accounts are prepared in accordance with the provisions of Part 2 of this schedule and that on their preparation the draft Completion Accounts shall be delivered to the Sellers for review in accordance with paragraph 2 of this schedule.
5. In order to enable the Sellers to review the draft Completion Accounts, the Purchaser shall procure that:
 - (a) the Purchaser's advisers and/or representatives shall use all reasonable efforts to provide promptly upon request such information and explanations as they may request during the course of their review of the draft Completion Accounts;
 - (b) the Sellers and the Sellers' advisers and/or representatives are given all reasonable access at all reasonable times and without delay to the books, records and working papers in their or their adviser's respective possession or control relating to the Group and to all its staff and shall permit the Sellers and the Sellers' advisers and/or representatives to take copies of such books and records; and
 - (c) generally provide the Sellers and the Sellers' advisors with such other information and assistance that they may reasonably require and in a timely fashion.
6. Unless the Sellers' Representatives serve a written notice (the "**Notice**") on the Purchaser within [***] Business Days of delivery of the draft Completion Accounts pursuant to paragraph 2 that they do not accept the same, the parties shall at the end of that period be deemed to have accepted such draft Completion Accounts which shall then be final and binding on the parties and which together shall be the Completion Accounts for the purposes of this Agreement. For the avoidance of doubt, any line items not identified in the Notice as being in dispute will be deemed to be agreed for the purposes of this Agreement and will therefore be final and binding upon the parties, to the extent where such line item should be changed as a direct consequence of the agreement or determination of a disputed line item.
7. A Notice (if any) served in accordance with paragraph 6 shall specify particulars of the dispute and any adjustments proposed to be made to the draft Completion Accounts.
8. If the Sellers' Representatives serve a Notice, then the Sellers' Representatives and the Purchaser shall each use all reasonable endeavours to reach agreement upon the matter or matters in dispute. If agreement on all disputed matters cannot be reached within [***] Business Days of the date of the Notice, any matter still in dispute may upon the direction of

any party be referred to an Independent Expert for determination in accordance with sub-clause 19.11 and this Schedule 9.

9. Upon the agreement or determination (as the case may be) of the disputed matter(s), such draft Completion Accounts shall then be the Completion Accounts for the purposes of this Agreement.
10. Subject to sub-clause 19.11(k), the costs of the Sellers' advisors in relation to all matters arising from this schedule shall be borne by the Sellers and the costs of the Purchaser's advisors in relation to all matters arising from this schedule shall be borne by the Purchaser.

Part 2
(Basis of Preparation)

[**]

Part 3
(Illustration of Cash and Debt, as at 31 October 2022)

[**]

Schedule 10

Part 1

(Calculation of Earn-out Consideration)

1. For the purposes of this Schedule 10, the following definitions shall apply:

"Aggregate Earn-out Payment" means the aggregate of the Earn-out Consideration payable in cash to the Sellers entitled to receive the Earn-out Consideration in accordance with this Schedule 10.

"Budget" means any operating and capital budget and cash flow forecast of the Group Companies.

"Business Plan" means any business plan of the Group Companies.

"Earn-out Consideration" means the aggregate of:

- (a) the Employee Earn-out Payment (if any);
- (b) the IND Earn-out Payment (if any);
- (c) the Project Earn-out Payment (if any);
- (d) the Publication Earn-out Payment (if any); and
- (e) the QR Earn-out Payment (if any),

up to a maximum payment equal to the pro-rata amount of £[***].

"Employee Earn-out Payment" means the aggregate payment of up to the pro-rata amount of £[***], to be paid in up to [***] equal tranches, each tranche being conditional upon satisfaction of an Employment Milestone.

"Employment Milestone" means each of the following employment related milestones:

- (a) each of the following executives of the Group remain employed by the Purchaser or the Group for the duration of the Earn-out Period:
 - (i) [***];
 - (ii) [***];
 - (iii) [***]; and
 - (iv) [***];
- (b) no less than [***]% of the Key Employees remain employed by the Purchaser or the Group for the duration of Earn-Out Period; and
- (c) the Hiring Target being achieved in accordance with the terms and conditions set out therein,

(together the **"Employment Milestones"** and each an **"Employment Milestone"**).

"Gross Margin" means, in respect of revenue of the Group, the amount equal to (i) the difference between revenue of the sale of a product or a service and direct costs related to such product or service sold (which direct costs are the salaries and other direct HR costs of the individuals working on such products or services (pro-rata to the time spent on the relevant project), the costs of delivery and/or distribution, costs of customer support services to the extent such customer support services are covered by revenues received, and the cost of cloud or internal cluster provision in connection with the relevant product or service); divided by (ii) revenue of the sale of such product or service.

"Hiring Target" means the Group, by the end of the [***] year period following Completion, employing in aggregate [***] full-time employees (for the avoidance of doubt excluding interns), or such other number of employees as may agreed from time to time in writing between the FME Shareholders' Representative and the Purchaser.

"IND Earn-out Payment" means the maximum aggregate payment of up to the pro-rata amount of £[***], to be paid in tranches of £[***], each tranche being conditional upon satisfaction of one IND Milestone [***].

"IND Milestones" means, [***].

"Lighthouse Projects" means [***] (and examples of such Lighthouse Projects include [***]).

"Milestones" means:

- (a) the Employment Milestones;

- (b) the IND Milestones;
- (c) the Project Milestones;
- (d) the Publication Milestones; and
- (e) milestones for the QR Earn-Out Payment,

and "**Milestone**" means each of them.

"Project Earn-out Payment" means the maximum aggregate payment of up to the pro-rata amount of £[***], to be paid in equal tranches of this amount divided by [***], each tranche being conditional upon satisfaction of one Project Milestone.

"Project Milestones" means completion of Lighthouse Projects during the Earn-Out Period, each of which Lighthouse Project satisfies the following requirements (each a "**Project Milestone**"):

- (a) the Lighthouse Project must utilise no less than the equivalent of [***] Working Days where each "**Working Day**" is defined as an employee of the Company working on a full-time basis during normal business hours on a business day;
- (b) the Lighthouse Project must not utilise [***];
- (c) the Lighthouse Project must achieve its written, quantifiable success objectives, in each case defined prior to initiation of the relevant Lighthouse Project, and any final reports and project deliverables are actually delivered; and
- (d) such other project-specific targets as may be agreed in writing between the FME Shareholders' Representative and the Purchaser from time to time (for the avoidance of doubt, if no additional project-specific targets have been so agreed in writing, then the Project Milestone shall otherwise be achieved if the relevant Lighthouse Project satisfies the requirements in items (a) to (c) (inclusive) above),

provided that if the same Lighthouse Project spans over [***] years, it shall be counted up to [***] times, one for each [***] days' time-period, beginning on Completion and ending on the [***] anniversary of Completion, provided that the requirements at paragraphs (a) to (d) above are met in respect of each relevant [***] day time-period during which the Lighthouse Project occurs.

"Publication Earn-out Payment" means the maximum aggregate payment of up to the pro-rata amount of £[***], to be paid in [***] tranches, each tranche being conditional upon satisfaction of a Publication Milestone and compliance with paragraph 4 below.

"Publication Milestones" means each of the following:

[***]

(and each a "**Publication Milestone**").

"QR Earn-out Payment" means the payment of up to the pro-rata amount of £[***], made up of the following:

- (a) [***]% of any Qualifying Revenue generated by the Group during the Earn-Out Period from any InstaDeep-BioNTech partnered programs ([***], but excluding [***]); and
- (b) [***]% of any revenue generated by the Group during the Earn-out Period from [***] or any other contracts and/or programs (excluding, for the avoidance of doubt, any InstaDeep-BioNTech partnered programs referred to in paragraph (a) above of this definition).

"Qualifying Revenue" means revenue in respect of which the Company has achieved at least a [***]% Gross Margin.

2. In the context of the calculation of each relevant maximum earn-out payment amount (in the definition of Earn-Out Consideration and in the definition of each category of earn-out payment), references to "**pro rata**" are to the percentage of total share capital in the Company held in aggregate by the FME Shareholders immediately prior to Completion, as set out in the Completion Allocation Schedule.
3. Subject to any adjustment required pursuant to paragraph 4 below, the Earn-out Consideration shall be the payment in cash of the Aggregate Earn-out Payment to such Sellers as are entitled to receive the Earn-out Consideration in accordance with sub-clause 4.2(b)(ii) of this Agreement.
4. The Aggregate Earn-out Payment shall be payable to each of the Sellers within [***] Business Days of the end of the Earn-out Period, in the proportion set opposite his or her name in the Completion Allocation Schedule.

5. The Milestones may be amended from time to time during the Earn-out Period by agreement between the FME Shareholders' Representative and the Purchaser.
6. In respect of the Publication Earn-out Payment and Publication Milestone, with the purpose of compliance with the Purchaser's policy in respect of publications relating to Intellectual Property, the Purchaser shall be notified by the Company in advance of any relevant publication being made, and shall have a right to review and make any reasonable editorial amendments to the relevant publication, such review and comment to be provided by the Purchaser within [***] Business Days of receipt of such notification (such [***] Business Day period may be extended by a further [***] Business Day period by the Purchaser in its sole discretion if the Purchaser considers that an Intellectual Property filing may be required).
7. The Founder Sellers severally undertake to and covenant with the Purchaser that during the Earn-out Period they shall exercise their powers as managers and employees (as applicable) of the Group (unless otherwise agreed in writing by the Purchaser) to ensure that:
 - 7.1 the business of the Group is carried on in the ordinary and proper course and substantially in the same manner that such business has been carried on prior to Completion, subject to any adjustments as may be implemented upon the agreement of the Founder Sellers and the Purchaser as a result of the Group becoming part of the Purchaser's group and the Purchaser's desired direction;
 - 7.2 the terms of the Post-Completion Management Agreement are complied with; and
 - 7.3 the Group's affairs are conducted so far as reasonably possible to foster the long-term success of the Group.
8. The Purchaser undertakes with the Sellers that, during the Earn-Out Period, it:
 - (a) shall not take any actions, or omit to take any actions, with the purpose of depriving the Sellers of any Contingent Consideration that may otherwise be payable in accordance with this Agreement;
 - (b) shall exercise its powers as shareholder to procure that the Founder Sellers are in a reasonable position to fully comply with their undertakings under paragraph 7 above and to achieve the Milestones;
 - (c) shall procure that none of the following matters is effected by the Company (or any other Group Company) without prior written consent of the Founder Sellers (such consent not to be unreasonably withheld or delayed):
 - (i) adoption of any Budget in respect of any financial year, and any material amendment of and/or deviation from it ('material' in this context being changes in excess of £[***]);
 - (ii) adoption of any Business Plan in respect of any financial year, and any material update and/or amendment of the same ('material' in this context being changes in excess of £[***]); and
 - (iii) dismissal of any Key Employee by the relevant Group Company, other than for cause;
 - (d) shall procure that the Founder Sellers are, subject always to the Purchaser's group policies from time to time, empowered to procure or direct the Company (or any other Group Company) to effect any of the following matters without prior written consent of the Purchaser:
 - (i) any pre-approved matters being those set out in the Budget from time to time (which shall include, for the avoidance of doubt, annual allocations for bonuses to new and existing employees);
 - (ii) in connection with the IND Milestones, the Project Milestones and/or the milestones for the QR Earn-Out Payment, incur any reasonable and proper capital expenditure (including obligations under hire-purchase and leasing arrangements), unless it exceeds the amount for capital expenditure in the relevant capital expenditure of the Budget by more than [***]% or (where no items were specified but a general provision made) exceeding £[***] whether individually or in the aggregate; and
 - (iii) in connection with the Employment Milestones, appoint, remove, or alter the compensation of any employee (where such alteration is indexed to bench-marked salary reports commonly used in the relevant industry with regard to AI/ML engineering (e.g. Radford <https://radford.aon.com/surveys/>) and reflect local hiring conditions) and in any case such alterations do not exceed per annum the higher of (i) [***]%; and (ii) [***]% above the level of inflation in the

country of the employing Group Company in the relevant year, unless his/her gross annual salary exceeds £[***].

Part 2
Key Employees

[**]

SCHEDULE 2

Redline of Amended Agreement

[**]

*** Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) the type of information that the Registrant treats as private or confidential.

EXECUTION VERSION
CONFIDENTIAL

LICENSE AND COLLABORATION AGREEMENT

This License and Collaboration Agreement (this “**Agreement**”), effective as of March 17, 2023 (the “**Execution Date**”), is entered into by and between BioNTech SE, a public limited company in the form of a Societas Europaea organized under the laws of the Federal Republic of Germany, with its corporate seat at An der Goldgrube 12 55131 Mainz, registered with the commercial register of the Local Court of Mainz under HRB 48720 (“**BioNTech**”), and OncoC4, Inc., a Delaware corporation having business offices at 9640 Medical Center Drive, Rockville, MD 20850 (“**OncoC4**”). OncoC4 and BioNTech are each referred to herein, individually, as a “**Party**” and, collectively, as the “**Parties**.”

RECITALS

WHEREAS, OncoC4 Controls certain Patents and Know-How relating to certain antibody compounds and products including the product candidates known as “ONC-392” and “AI-061” (each, as defined below);

WHEREAS, BioNTech wishes to obtain from OncoC4 and OncoC4 wishes to grant to BioNTech, an exclusive license under the relevant Patents and Know-How Controlled by OncoC4 to Exploit the Licensed Compounds and Licensed Products comprising or containing Licensed Compounds in the Field in the Territory (as all such initially capitalized terms are defined below), in each case, in accordance with the terms and conditions more particularly set forth herein;

WHEREAS, BioNTech wishes to obtain from OncoC4 and OncoC4 wishes to grant to BioNTech, an exclusive option to obtain an exclusive license under the relevant Patents and Know-How Controlled by OncoC4 to Exploit AI-061 Products (defined below) in the Field in the Territory, in each case, in accordance with the terms and conditions more particularly set forth herein; and

WHEREAS, in connection with the foregoing, the Parties wish to enter into a collaboration for certain joint Development of Licensed Compounds and Licensed Products, in accordance with the terms and conditions more particularly set forth herein, while other Development of Licensed Compounds and Licensed Products (including any Development of combinations of ONC-392 with other products owned or controlled by BioNTech) would, as between the Parties, be conducted by BioNTech.

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

ARTICLE I **DEFINITIONS**

Unless otherwise specifically set forth herein or the context otherwise requires, the following capitalized terms have the respective meanings set forth below (and derivative forms of such terms shall be interpreted accordingly):

1.1. “**Accounting Standards**” means, with respect to a Person, GAAP (generally accepted accounting principles as practiced in the United States) or IFRS (International Financial Reporting Standards), in each case, as generally and consistently applied by such Person and its Affiliates.

1.2. “[***]” means, collectively, [***].

1.3. “**Action**” means any claim, action, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, and whether civil or criminal), assessment, arbitration, investigation, hearing, charge, complaint, demand, notice or proceeding of, to, from, by or before any Governmental Authority.

1.4. “**Affiliate**” means, with respect to a Person, any entity controlling, controlled by or under common control with such first Person at the time that the determination of affiliation is made and for as long as such control exists. For purposes of this definition, “control” means (a) direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors of such Person (or if the jurisdiction where such Person is domiciled prohibits foreign ownership of such entity, the maximum foreign ownership interest permitted under such Laws; *provided*, that such ownership interest provides actual control over such Person), (b) status as a general partner in any partnership, or (c) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Affiliates of a Party will exclude Persons who are financial investors of such Party or under common control of such financial investors other than such Party and its subsidiary entities.

1.5. “**AI-025**” means the Anti-PD-1 Antibody Developed by [***] and known as “AI-025,” as of the Execution Date, [***].

1.6. “**AI-025 Know-How**” means any Know-How relating to AI-025 licensed or assigned to OncoC4 pursuant to the AI License.

1.7. “**AI-025 Patent**” means [***].

1.8. “**AI-061**” means the biopharmaceutical composition containing as its sole active ingredients both ONC-392 and AI-025, [***] that is known as “AI-061,” as of the Execution Date, as further described on Schedule 1.8.

1.9. “**AI-061 Product**” means any biopharmaceutical composition containing as its sole active ingredients both ONC-392 and AI-025, [***] including, any biopharmaceutical composition containing as its sole active ingredient AI-061.

1.10. “**AI Agreements**” means, collectively, those certain (a) AI-025/AI-061 License and Assignment Agreement, dated on or about the Execution Date, between [***] and OncoC4 (the “**AI License**”); (b) 392 Collaboration Termination and Assignment Agreement, dated on or about the Execution Date, between [***] and OncoC4 (“**392 Collaboration Termination**”) and (c) 392 License Termination and Assignment Agreement, dated on or about the Execution Date between [***] and OncoC4 (“**392 License Termination**”).

1.11. “**Antibody**” means:

[***]

1.12. “**Anti-CTLA-4 Antibody**” means [***].

1.13. “**Anti-PD-1 Antibody**” means [***].

1.14. “**BioNTech Competitor**” means [***].

1.15. “**BioNTech Product**” means any product owned or controlled by BioNTech or its Affiliate (for clarity, other than pursuant to this Agreement) that is (a) an Other Active used in a Combination Product with the Licensed Compound or (b) is used as part of a combination regimen with the Licensed Compound.

1.16. “**BioNTech Technology**” means any Patents or Know-How (a) conceived, discovered, developed, reduced to practice, or otherwise made by or on behalf of BioNTech, its Affiliates and Sublicensees under this Agreement, or (b) to the extent not otherwise covered in subsection (a), Controlled by BioNTech, its Affiliates or Sublicensees as of the Effective Date or during the Term, and is necessary or reasonably useful for OncoC4 to perform its obligations under the CDP; *provided*, that [***].

1.17. “**Biosimilar Competition**” means, [***].

1.18. “**Biosimilar Material Competition**” means [***].

1.19. “**Biosimilar Product**” means, [***].

1.20. “**BLA**” means: a Biologics License Application (as more fully described in 21 C.F.R. Part 601, or its successor regulation) filed with the FDA; including, all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect thereto.

1.21. “**BNT PD-1 License**” has the meaning set forth in Section 3.1(b).

1.22. “**Business Day**” means any day, other than a Saturday, a Sunday, or any day on which commercial banks in New York, New York or Mainz, Germany, are authorized or required by applicable Law to remain closed.

1.23. “**Calendar Quarter**” means each of the three month periods ending on March 31, June 30, September 30, and December 31 of any Calendar Year; *provided*, that: (a) the first Calendar Quarter of the Term will extend from the Effective Date to the end of the Calendar Quarter in which the Effective Date occurs; and (b) the last Calendar Quarter of the Term will extend from the beginning of the Calendar Quarter in which this Agreement expires or terminates until the effective date of such expiration or termination.

1.24. “**Calendar Year**” means, for the first Calendar Year of the Term, the period beginning on the Effective Date and ending on December 31 of the year in which the Effective Date occurs, and for each Calendar Year thereafter each twelve (12) month period commencing

on January 1 and ending on December 31, except that the last Calendar Year of the Term will commence on January 1 of the year in which this Agreement expires or terminates and end on the effective date of such expiration or termination.

1.25. “**CD80/CD86 Compound**” means [***].

1.26. “**Change of Control**” means, with respect to a Party, (a) a merger, consolidation, reorganization, amalgamation, arrangement, share exchange, tender or exchange offer, private purchase, business combination or other transaction of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity or the parent or ultimate parent of the surviving entity immediately after such merger or consolidation, or the foregoing occurs with respect to a parent or ultimate parent company of such Party, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates (if any), becomes the direct or indirect beneficial owner of more than fifty percent (50%) of the combined voting power of the outstanding securities of such Party or any Affiliate directly or indirectly controlling such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party’s assets. Notwithstanding the foregoing, any transaction or series of transactions effected for the primary purpose of financing the operations of the applicable Party or changing the form or jurisdiction of organization of such Party will not be deemed a “Change of Control” for purposes of this Agreement, *provided*, that if the transaction would otherwise fall within clause (a) or (b) of this definition, the entity with direct or indirect beneficial ownership of fifty percent (50%) or more of the combined voting power of the surviving entity or the parent or ultimate parent of the surviving entity is a financial investor that is not an operating pharmaceutical or biopharmaceutical company and is not controlled by or under common control with such an entity.

1.27. “**Claims**” means, with respect to a particular item or product and a particular Patent, that such Patent claims the composition of such item or product or any of its ingredients or formulations; a method of making or using it or them; or an item used or present in the manufacture of such item or product (including plasmids, vectors, cell lines, and chemical intermediates, as applicable).

1.28. “**Clinical Data**” means the original human subject data and case report forms (CRFs) collected or generated with respect to Clinical Trials of any Licensed Product, together with all analysis, reports, and results with respect thereto.

1.29. “**Clinical Trial**” means a study in which human subjects or patients are dosed with a drug or biologic, whether such drug or biologic is approved or investigational.

1.30. “**Combination Product**” means [***].

1.31. “**Commercialization**” means any and all activities related to the commercialization of a product, including the pre-marketing, launching, marketing, promotion (including advertising and detailing), market research, labeling, bidding and listing, pricing and reimbursement, distribution, storage, handling, Manufacturing for commercial sale (including inventory build to support launch), offering for sale, selling, having sold, importing and

exporting for sale, having imported and exported for sale, distribution, having distributed, order processing, handling returns and recalls, customer service and support, and post-marketing safety surveillance and reporting of a product, as well all regulatory compliance and conduct of administrative functions with respect to the foregoing. For clarity, "Commercialization" includes all pre-launch marketing and other launch preparation activities, including training of personnel who will conduct Commercialization activities, as well as Manufacturing activities in preparation for and to establish and maintain commercial sales. When used as a verb, "Commercialize" means to engage in Commercialization.

1.32. "**Commercially Reasonable Efforts**" means [***].

1.33. "**Compulsory License**" means, with respect to a Licensed Product and a given country or jurisdiction, a right for a Third Party to develop, make, have made, use, sell, offer for sale or import a Licensed Product where such right has been obtained as a result of a licensing requirement or obligation under applicable Law or an order of a Governmental Authority in such country or jurisdiction.

1.34. "**Confidential Information**" means (i) all trade secrets or confidential or proprietary information (including any tangible materials embodying any of the foregoing) of the disclosing Party or its Affiliates provided or disclosed to the other Party in connection with this Agreement; and (ii) the terms and conditions of this Agreement; *provided, however*, that Confidential Information will not include information that:

(a) has been published by a Third Party or otherwise is or hereafter becomes publicly known by public use, publication, general knowledge or the like through no breach of this Agreement on the part of the receiving Party;

(b) has been in the receiving Party's possession prior to disclosure by the disclosing Party hereunder, and not through a prior disclosure by the disclosing Party, without any obligation of confidentiality with respect to such information (as evidenced by the receiving Party's or such Affiliate's written records or other competent evidence);

(c) is subsequently received by the receiving Party from a Third Party who is not known by the receiving Party to be under an obligation of confidentiality to the disclosing Party under any agreement between such Third Party and the disclosing Party; or

(d) has been independently developed by or for the receiving Party without reference to, or use or disclosure of, the disclosing Party's Confidential Information (as evidenced by the receiving Party's or such Affiliate's written records or other competent evidence);

provided, further, that clauses (b) through (d) above will not apply to the terms and conditions of this Agreement.

Licensed Know-How, unpublished Licensed Patents, [***] and the terms and conditions of this Agreement shall be deemed the Confidential Information of both Parties, with each Party treated as the receiving Party in respect thereof.

1.35. “**Control**” or “**Controlled**” means, with respect to any Know-How, Patent, Regulatory Material, Regulatory Approval or other property right, the legal authority or right (whether by ownership, license (other than a license granted pursuant to this Agreement) or otherwise) of a Person or its Affiliate to grant access, a license, or a sublicense of or under such Know-How, Patent, Regulatory Material, Regulatory Approval or other property right, without breaching the terms of any agreement with a Third Party. Notwithstanding the foregoing, Patents and Know-How licensed to OncoC4 under the Upstream Agreement(s) shall be deemed to be “Controlled” by OncoC4 for purposes of this Agreement to the same extent that such Patents and Know-How are licensed to OncoC4 and otherwise fall within the definition of Licensed Patents and Licensed Know-How, respectively.

1.36. “**Cover**,” “**Covering**” or “**Covered**” mean, [***].

1.37. “**CTLA-4**” means [***].

1.38. “**Development**” means non-clinical, pre-clinical, and clinical drug research and development activities, whether before or after Regulatory Approval, including drug metabolism and pharmacokinetics, translational research, toxicology, pharmacology, test method development and stability testing, process and packaging development and improvement, process validation, process scale-up, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, conduct of Clinical Trials, regulatory affairs, the preparation and submission of Regulatory Materials, Clinical Trial regulatory activities, and any other activities directed towards obtaining or maintaining Regulatory Approval of any Licensed Product, including Manufacturing in support of any of the foregoing. Development includes use and importation of the relevant Licensed Product to conduct such Development activities. For clarity, “Development” will not include Commercialization activities. When used as a verb, “Develop” means to engage in Development.

1.39. “**Dollars**” means United States dollars.

1.40. “**EU**” means the European Union, as its membership may be constituted from time to time, and any successor thereto, and the United Kingdom.

1.41. “**Exploit**” means, with respect to a pharmaceutical or biologic product, to Develop, Manufacture, make, have made (subject to the terms of this Agreement, if applicable), Commercialize, use, sell, offer for sale, import, export, and otherwise exploit such Licensed Product.

1.42. “**FDA**” means the United States Food and Drug Administration or any successor agency thereto.

1.43. “**FFDCA**” means the U.S. Federal Food, Drug and Cosmetic Act.

1.44. “**Field**” means [***].

1.45. “**First Commercial Sale**” means [***].

1.46. “**FTE**” means the equivalent of a full-time individual’s work time for a twelve (12) month period devoted to Development (excluding management and indirectly related personnel’s time), where “full-time” is determined by [***] hours per Calendar Year. In the event that any individual who works full-time during a given Calendar Year works partially on the activities under this Agreement and partially on other work outside this Agreement, then the full-time equivalent to be attributed to such individual’s work hereunder for such Calendar Year shall be equal to the percentage of such individual’s total work time in such Calendar Year that such individual spent working on activities under this Agreement. For avoidance of doubt, FTE shall exclude individuals responsible for managerial, secretarial, clerical and administrative activities.

1.47. “**FTE Costs**” means, with respect to a Party for any period, the applicable FTE Rate multiplied by the applicable number of FTEs of such Party performing Development activities during such period in accordance with the CDP.

1.48. “**FTE Rate**” means [***] per FTE per Calendar Year; provided, that the FTE Rate will be prorated for the period beginning on the Effective Date and ending on December 31, 2023 [***].

1.49. “**Fully Burdened Manufacturing Costs**” or “**FBMC**” means the costs incurred by or on behalf of the Parties or their Affiliates in connection with Manufacturing or purchasing from a Third Party, as applicable, the Licensed Compound or Licensed Products (or components thereof). For quantities Manufactured by a Party or its Affiliate, FBMC shall be comprised of the following elements calculated in accordance with the applicable Accounting Standard: [***].

1.50. “**GCP**” means all applicable then-current standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable, (a) as set forth in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products, (b) the Declaration of Helsinki (2013) as last amended at the 64th World Medical Association in October 2013 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), and (d) the equivalent applicable Laws in any relevant country, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, safety, and confidentiality of trial subjects.

1.51. “**GLP**” means all applicable then-current standards for laboratory activities for pharmaceuticals, as set forth in the FDA’s Good Laboratory Practice regulations as defined in 21 C.F.R. Part 58, or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development (OECD), and such standards of good laboratory practice as are required by the equivalent applicable Laws in the relevant country and other organizations and governmental agencies in countries in which the Licensed Product is intended to be sold by the Party that is subject to such standards.

1.52. “**GMP**” means all applicable then-current standards for Manufacturing, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. §§ 210, 211 and 600-680 and all applicable FDA guidelines and requirements, (b) European Directive 2003/94/EC for medicines and investigational medicines for human use and the applicable guidelines stated in the EudraLex guidelines, (c) the principles detailed in the applicable ICH guidelines, (d) the conduct of an inspection by a Qualified Person (as defined therein) and the execution by such Qualified Person of an appropriate certification of inspection; and (e) the equivalent applicable Laws in any relevant country, each as may be amended and applicable from time to time.

1.53. “**Governmental Authority**” means any national, multinational, supranational, federal, state, local, provincial, municipal, foreign or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal, official or officer, in any case, exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority, or functions of any nature pertaining to government.

1.54. “**ICH**” means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.55. “**IND**” means an application filed with a Regulatory Authority for authorization to commence Clinical Trials, including (a) an Investigational New Drug Application as defined in the FDCA or any successor application or procedure filed with the FDA, (b) any equivalent thereof in other countries or jurisdictions, (e.g., a Clinical Trial Application (CTA) in the EU) and (c) all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.

1.56. “**Indemnified Party**” means a Person entitled to indemnification under ARTICLE XI.

1.57. “**Indemnifying Party**” means a Party from whom indemnification is sought under ARTICLE XI.

1.58. “**Indication**” means, [***].

1.59. “**Initiation**” means, with respect to a Clinical Trial, the date upon which the first patient or subject is dosed in such Clinical Trial.

1.60. “**Joint Development Costs**” means, [***].

1.61. “**Joint Development Program**” means the joint program of Development to be conducted under the CDP.

1.62. “**Know-How**” means all inventions, practices, methods, protocols, formulae, knowledge, know-how, trade secrets, instructions, processes, procedures, assays, skills, experiences, techniques, information, works of authorship, drawings, assembly procedures, computer programs, apparatuses, specifications, and Materials.

1.63. “**Law**” means any applicable federal, state, local, national, multinational, supranational, provincial, municipal, foreign, or other law, statute, legislation, constitution, principle of common law, code, treaty ordinance, regulation, rule, or order of any kind put into place by or under the authority of any Governmental Authority, together with any rules, regulations, or compliance guidance promulgated thereunder. For clarity, “Laws” include the applicable regulations and guidance of the FDA and European Union (and national implementations thereof) that constitute GLP, GMP, and GCP (and, if and as appropriate under the circumstances, ICH guidance or other comparable regulations and guidance of any other applicable Governmental Authority).

1.64. “**Licensed Compound**” means each of (a) ONC-392, and (b) any and all Anti-CTLA-4 Antibodies Controlled by OncoC4 as of the Execution Date or during the Term (whether such Antibodies exist as of the Execution Date or arise during the Term) (including the ONC-392 backup molecules described on Schedule 1.64), in each case (clauses (a) and (b)), either in protein form or as a nucleotide sequence encoding the Antibody.

1.65. “**Licensed Know-How**” means any and all Know-How existing as of the Execution Date or arising during the Term and Controlled by OncoC4 or its Affiliates as of the Execution Date or during the Term that is necessary or reasonably useful for the Exploitation of the Licensed Compound and Licensed Products in the Field in the Territory; *provided*, that (a) the Licensed Know-How shall not include Know-How relating solely to an Other Active (other than AI-025) of a Combination Product unless otherwise mutually agreed by the Parties separately in writing, and (b) if BioNTech does not exercise the Option in accordance with Section 2.2, then upon and following the expiration of the Option Period, the Licensed Know-How shall exclude any Know-How relating solely to AI-061 or AI-025 unless otherwise mutually agreed by the Parties separately in writing.

1.66. “**Licensed Patents**” means (a) the Listed Patents and (b) any other Patents existing as of the Execution Date or arising during the Term that are Controlled by OncoC4 or its Affiliates as of the Execution Date or during the Term and that are necessary or reasonably useful for the Exploitation of the Licensed Compound and Licensed Products in the Field in the Territory; *provided*, that (i) Licensed Patents shall not include Patents solely claiming or solely covering an Other Active (other than AI-025) of a Combination Product unless otherwise mutually agreed by the Parties separately in writing, and (ii) if BioNTech does not exercise the Option in accordance with Section 2.2, then upon and following the expiration of the Option Period, the Licensed Patents shall exclude any Patents solely claiming or solely covering AI-061 or AI-025 unless otherwise mutually agreed by the Parties separately in writing.

1.67. “**Licensed Product**” means (i) any pharmaceutical or biologic product or composition that contains any Licensed Compound, including Combination Products, and (ii) subject to the terms and conditions of Section 2.2, the AI-061 Product; *provided*, that if BioNTech does not exercise the Option in accordance with Section 2.2 and Section 7.2 prior to the expiration of the Option Period, then upon and following the expiration of the Option Period, the AI-061 Product shall no longer be a Licensed Product under this Agreement unless otherwise mutually agreed by the Parties separately in writing. It is understood that Licensed Products may be in the following forms, presentations or applications: (a) a form consisting of the Licensed Compound as a single therapeutically active ingredient (“**Licensed Single Product**”); or (b) a Combination Product.

1.68. “**Listed Patents**” means (a) the Patents listed in Schedule 1.68; (b) all patents and patent applications (including provisional applications), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, re-issues, additions, renewals, extensions, confirmations, registrations, any other pre- or post-grant forms of any of the foregoing, (c) any confirmation patent or registration patent or patent of addition, utility models, patent term extensions, and supplemental protection certificates or requests for continued examinations, foreign counterparts, and the like of any of the foregoing, (d) any and all patents that have issued or in the future issue from the foregoing patent applications, including author certificates, utility models, petty patents, innovation patents and design patents and certificates of invention.

1.69. “**Losses**” means damages, losses, liabilities, costs (including costs of investigation, defense), fines, penalties, taxes, expenses, or amounts paid in settlement (in each case, including reasonable attorneys’ and experts’ fees and expenses), in each case resulting from an Action.

1.70. “**MAA**” means, with respect to a product and a country or jurisdiction, an application for marketing authorization for Commercialization of such product in such country or jurisdiction, including a BLA in the United States.

1.71. “**Major Market**” means any of the following countries: [***].

1.72. “**Manufacturing**” means all activities related to the production of Licensed Compound or Licensed Product, or any component or intermediate thereof, including the making, synthesis, conjugation, production, manufacture, having manufactured, processing, filling, finishing, packaging, labeling, shipping and holding of any intermediate thereof, including process development, process qualification and validation, scale-up, commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control. When used as a verb, “Manufacture” means to engage in Manufacturing activities. References to a Person engaging in Manufacturing activities will include having any or all of the foregoing activities performed by a Third Party to the extent such performance is permitted hereunder.

1.73. “**Materials**” means chemical and biological materials, including plasmids, constructs, and cell lines.

1.74. “[***] **Agreement**” means [***].

1.75. “**Net Sales**” means, with respect to any Licensed Product, the gross amount invoiced on sales of such Licensed Product by BioNTech or any of its Affiliates or Sublicensees to a Third Party, less the following customary deductions, determined in accordance with the Accounting Standards, to the extent allocated to the sale of such Licensed Product and actually taken, paid, accrued, allowed, or included in the gross sales prices or specifically allocated in its financial statements with respect to such sales:

[***]

Notwithstanding the foregoing, sales of the Licensed Product for clinical study purposes, bona fide charitable purposes, “compassionate use sales,” named patient sales (unpaid or at cost

or a no-profit price) or similar use, in each case, at or below cost, shall not constitute Net Sales. Sales and other transfers of Licensed Product between any of BioNTech, its Affiliates and Sublicensees (for clarity, including distributors) will not give rise to Net Sales, but rather the subsequent sale of Licensed Product to Third Parties will give rise to Net Sales. Net Sales will be determined in accordance with the Accounting Standards.

In the event that a Licensed Product is sold in any country in the form of a Combination Product, Net Sales of such Combination Product shall be adjusted by multiplying actual Net Sales of such Combination Product in such country during the relevant Calendar Quarter calculated pursuant to the foregoing definition of "Net Sales" by the fraction $A/(A+B)$, where "A" is the average invoice price in such country of any Licensed Product that contains the Licensed Compound, as applicable, as its sole active ingredient(s), if sold separately in such country, and "B" is the average invoice price in such country of each product that contains Other Active(s) contained in such Combination Product as its sole active ingredient(s), if sold separately in such country. If either a Licensed Product that contains the Licensed Compound, as applicable, as its sole active ingredient or a product that contains Other Active in the Combination Product as its sole active ingredient(s) is not sold separately in a given country during the relevant Calendar Quarter, prior to the date of the First Commercial Sale of such Combination Product, then: (a) if they are each sold separately in any Major Market, BioNTech shall be entitled to apply worldwide the ratio obtained by using the prices in such Major Market in the $A/(A+B)$ formula; or (b) if (a) is not the case then the Parties shall negotiate in good faith and seek to reach mutual agreement on a reasonable adjustment to Net Sales in such country that takes into account the medical contribution to the Combination Product of, and all other factors reasonably relevant to the relative value of, the Licensed Compound, as applicable, on the one hand, and Other Active(s), on the other hand. If the Parties do not reach written agreement as to such adjustment within thirty (30) days after BioNTech requests in writing such negotiations, then BioNTech may invoke and the Parties shall follow the Expert Valuation procedure set forth in Schedule 1.75 to determine such adjustment. Notwithstanding the foregoing or anything contained herein, for purposes of calculating Net Sales, AI-061 Products shall be deemed to be a Licensed Single Product (except where combined with [***] or more Other Actives) and shall not be deemed to be a Combination Product. For purposes of calculating royalties due under an Upstream Agreement, the definition of Net Sales shall not be adjusted for purposes of calculating Net Sales hereunder and the amounts due by BioNTech under this Agreement. However, recognizing that OncoC4 may owe royalties under an Upstream Agreement based on a different Net Sales definition, BioNTech shall provide or cause to be provided to OncoC4 such information as OncoC4 may reasonably request to enable OncoC4 to properly report and pay royalties under, and otherwise comply with, the Upstream Agreements.

1.76. "**Non-Rare Cancer Indication**" means an Indication in oncology for a cancer that is not a Rare Cancer.

1.77. "**ONC-392**" means the monoclonal Anti-CTLA-4 Antibody Developed by OncoC4 and known as "ONC-392," as of the Execution Date, the amino acid sequence of which is set forth on Schedule 1.77.

1.78. "**Option Period**" means the period commencing on the Effective Date and ending on the date [***] following Completion of the first Phase 1 Trial of AI-061. As used herein, "**Completion of the first Phase 1 Trial of AI-061**" means the date upon which the final subject

enrolled in such Clinical Trial completed the safety and the efficacy assessment (as such Clinical Trial is described in the initial CDP), whether the Clinical Trial concluded according to the pre-specified protocol or was terminated; *provided*, that if the protocol for such Clinical Trial is amended to significantly increase the number of subjects or otherwise become a “Phase 2 Trial” (including a “Phase 1/2” Clinical Trial), then “Completion of the first Phase 1 Trial of AI-061” shall be deemed to be the earlier of (i) the date upon which the final subject enrolled in the “Phase 1” portion of such Clinical Trial completed the safety and the efficacy assessment, and (ii) the date upon which the first subject in the “Phase 2” portion of such Clinical Trial is dosed. As used in this definition, “completed the safety and the efficacy assessment” means, with respect to the final subject enrolled in a Clinical Trial, (A) the first date upon which both Parties have received Clinical Data from the first tumor response assessment for such final subject in such Clinical Trial or the relevant portion thereof and (B) a first summary of all safety, efficacy, pharmacokinetic and biomarker data collected as of the first tumor response assessment for such final subject in such Clinical Trial or the relevant portion thereof is available.

1.79. “[***]” means [***].

1.80. “**Out-of-Pocket Costs**” means, with respect to a Party, costs and expenses paid by such Party or its Affiliate to Third Parties (or payable to Third Parties and accrued in accordance with Accounting Standards), other than employees of such Party or its Affiliates.

1.81. “**Patents**” means (a) all patents and patent applications (including provisional applications), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, re-issues, additions, renewals, extensions, confirmations, registrations, any other pre- or post-grant forms of any of the foregoing, (b) any confirmation patent or registration patent or patent of addition, utility models, patent term extensions, and supplemental protection certificates or requests for continued examinations, foreign counterparts, and the like of any of the foregoing, (c) any and all patents that have issued or in the future issue from the foregoing patent applications, including author certificates, utility models, petty patents, innovation patents and design patents and certificates of invention.

1.82. “**PD-1**” means programmed cell death protein 1 and is also known as “CD279” or the cluster of differentiation 279.

1.83. “**PD-1 Product**” means any biopharmaceutical composition that contains an Anti-PD-1 Antibody.

1.84. “**Person**” means any natural person, corporation, general partnership, limited partnership, joint venture, proprietorship or other business organization or a Governmental Authority.

1.85. “**Phase 1 Trial**” means a Clinical Trial of a Licensed Product that generally provides for the first introduction into humans of such Licensed Product, with the primary purpose of determining metabolism, pharmacokinetic properties, the maximum tolerated dosage, and side effects of such product, in a manner that is generally consistent with 21 C.F.R. § 312.21(a), or a similar clinical study prescribed by the Regulatory Authorities in a country or jurisdiction outside the United States, excluding any investigator-initiated Clinical Trials. For

clarity, Phase 1 Trial includes any Clinical Trial (or portion thereof) designated as a “Phase 1a” Clinical Trial or “Phase 1b” Clinical Trial.

1.86. “**Phase 2 Trial**” means a Clinical Trial of a Licensed Product conducted on a sufficient number of subjects for evaluating (and the principal purpose of which is to evaluate) the effectiveness of such Licensed Product for its particular intended use and obtaining (and to obtain) information about side effects and other risks associated with the drug, in a manner that is generally consistent with 21 C.F.R. § 312.21(b), or a similar clinical study prescribed by the Regulatory Authorities in a country or jurisdiction outside the United States, to permit the design of further Clinical Trials of such Licensed Product, excluding any investigator-initiated Clinical Trials. For clarity, Phase 2 Trial includes any Clinical Trial (or portion thereof) designated as a “Phase 2a” Clinical Trial or “Phase 2b” Clinical Trial.

1.87. “**Phase 3 Trial**” means a Clinical Trial of a Licensed Product with a defined dose or a set of defined doses of such Licensed Product and conducted on a sufficient number of subjects for ascertaining (and that is designed to ascertain) the overall risk-benefit relationship of the Licensed Product for its intended use and determining (and to determine) warnings, precautions, and adverse reactions that are associated with such Licensed Product in the dosage range to be prescribed, in a manner that is generally consistent with 21 C.F.R. § 312.21(c), or a similar clinical study prescribed by the Regulatory Authorities in a country or jurisdiction outside the United States, which trial is necessary to support Regulatory Approval of such Licensed Product, excluding any investigator-initiated Clinical Trials. For clarity, Phase 3 Trial includes any Clinical Trial (or portion thereof) designated as a “Phase 3a” Clinical Trial.

1.88. “**Pivotal Trial**” means a Clinical Trial that is prospectively designed to demonstrate that a Licensed Product is safe and effective for use in a particular Indication in a manner sufficient to evaluate the overall benefit-risk relationship of the Licensed Product and to provide an adequate basis for physician labeling, and which, at the time of the initiation of such Clinical Trial, is intended and expected to be the basis for Regulatory Approval by the FDA and/or the European Commission after EMA opinion in the EU of such Licensed Product for such Indication, based on discussions with the relevant Regulatory Authority. For clarity, Pivotal Trial shall (a) always include Phase 3 Trials, and (b) include “Phase 2b/3” Clinical Trials (or the appropriate portion thereof), Phase 2 Trials, “Phase 1/2” Clinical Trials, or other Clinical Trials, if the conditions of this definition are met. In some cases, it may not be known whether a given Phase 2 Trial will be treated by the governing Regulatory Authority as a Pivotal Trial until after it is completed. In these cases, if such a Phase 2 Trial is ultimately agreed by the governing Regulatory Authority to be a Pivotal Trial, then from such point forward it will be treated as a Pivotal Trial for purposes of this Agreement, and any milestones hereunder that become due based on such status will be deemed achieved only as of the date of such agreement from such governing Regulatory Authority (and any associated payment due hereunder will not be considered late based on earlier events in relation to such Clinical Trial prior to such agreement from such governing Regulatory Authority to treat it as a Pivotal Trial).

1.89. “**Pricing and Reimbursement Approval**” means, with respect to a Licensed Product, the governmental approval, agreement, determination or decision establishing the price or level of reimbursement for such Licensed Product, in a given country in the Territory.

1.90. “**Prosecution**” means, in relation to any Patents (a) to prepare and file patent applications, including re-examinations or re-issues thereof, and represent applicants or assignees before relevant patent offices or other relevant Governmental Authorities during examination, re-examination and re-issue thereof, in appeal processes and interferences, or any equivalent proceedings, (b) to defend all such applications against Third Party oppositions or other challenges, (c) to secure the grant of any patents arising from such patent application, (d) to maintain in force any issued patent (including through payment of any relevant maintenance fees), and (e) to make all decisions with regard to any of the foregoing activities. When used as a verb, “Prosecute” means to engage in Prosecution activities.

1.91. “**Rare Cancer**” means any cancer that affects fewer than 40,000 people per year in the U.S. based on NCI data.

1.92. “**Regulatory Approval**” means the final or conditional approval of the applicable Regulatory Authority necessary for the marketing and sale of the Licensed Product in the Field in a country or jurisdiction in the Territory, including BLA approval in the United States, but excluding any separate Pricing and Reimbursement Approval.

1.93. “**Regulatory Authority**” means any national, multinational, supranational, federal, state, local, provincial, municipal, foreign or other regulatory agency, department, bureau or other Governmental Authority with authority over the clinical development, manufacture, marketing or sale of the Licensed Product in a country.

1.94. “**Regulatory Commitments**” means activities to be performed by or on behalf of a Party or its Affiliates in connection with seeking Regulatory Approval of a Licensed Product in the Territory, but excluding, for clarity, any post-marketing commitments as mandated or agreed to be conducted with a Regulatory Authority for such Licensed Product.

1.95. “**Regulatory Materials**” means, with respect to a Licensed Product, (a) all INDs, MAAs, BLAs, establishment license applications, drug master files, applications for designation as an “Orphan Product” under the Orphan Drug Act, for “Fast Track” status under Section 506 of the FDCA (21 U.S.C. § 356) or for a Special Protocol Assessment under Section 505(b)(4)(B) and (C) of the FDCA (21 U.S.C. § 355(b)(4)(B) and (C)) and all other similar filings (including counterparts of any of the foregoing in any country in the Territory), (b) any applications for Regulatory Approval and other applications, filings, dossiers, or similar documents (e.g., pediatric investigation plans) submitted to a Regulatory Authority in any country for the purpose of obtaining Regulatory Approval from that Regulatory Authority, (c) all supplements and amendments to any of the foregoing, and (d) all data, including Clinical Data, and other information contained in, and Regulatory Authority correspondence relating to, any of the foregoing.

1.96. “**Senior Officers**” means: (a) with respect to OncoC4, the Chief Executive Officer or any other officer on the management team (such as Chief Operating Officer or the Chief Medical Officer) of OncoC4 or his/her designee or successor with appropriate decision-making authority; and (b) with respect to BioNTech, the Senior Vice-President (or any more senior position thereto) of BioNTech or his/her designee or successor with appropriate decision-making authority.

1.97. “**Service Provider**” means, with respect to OncoC4, any Third Party service provider acting on behalf of OncoC4 or its Affiliate, on a fee for service basis, in the performance of activities conducted in accordance with the CDP; *provided*, that “Service Providers” shall not include (a) Third Parties engaged to supply Licensed Compounds or Licensed Products to either Party, (b) Third Parties performing material services expected to receive consideration from either Party in excess of [***] in any Calendar Year, (c) any Third Party that has failed to satisfy a quality audit required under a customary quality agreement in place between the Parties or their Affiliates and such failure has not been cured within sixty (60) days of notice to the Third Party of such failure or (d) Third Parties engaged to apply for regulatory approvals or authorized to make payments or other transfers of value to other Third Parties, in particular, but not limited to, government officials, public authorities, healthcare organizations, healthcare professionals, patient advocacy groups or patients.

1.98. “**Stage 2**” means that second portion of the Phase 3 Trial for the NSCLC 2L Monotherapy described in the CDP utilizing a single recommended dose of the Licensed Product, subject to approval by the independent data monitoring committee (DMC) overseeing such Phase 3 Trial, or otherwise requested or recommended by the FDA.

1.99. “**Sublicense**” means a grant of rights from BioNTech to a Sublicensee under any of the rights licensed to BioNTech by OncoC4 under Section 2.1, for clarity excluding contract research organizations, contract manufacturing organizations, and other service providers that do not obtain commercial rights (i.e., the right to sell to anyone but BioNTech, a BioNTech Affiliate or an entity deriving rights from them).

1.100. “**Sublicensee**” means, with respect to a Party, a Third Party sublicensee of rights granted to such Party under this Agreement, or any further sublicensee of such rights (regardless of the number of tiers, layers or levels of sublicenses of such rights), for clarity excluding grants to contract research organizations, contract manufacturing organizations, and other service providers that do not obtain commercial rights (i.e., the right to sell to anyone but BioNTech, a BioNTech Affiliate or an entity deriving rights from any of them).

1.101. “**Territory**” means the entire world.

1.102. “**Third Party**” means any Person other than a Party or their respective Affiliates.

1.103. “**Trademark**” means all registered and unregistered trademarks, service marks, trade dress, trade names, logos, insignias, domain names, symbols, designs, and combinations thereof.

1.104. “**United States**” or “**U.S.**” mean the United States of America and its territories and possessions.

1.105. “**Upstream Agreements**” means the agreements set forth on Schedule 1.105 pursuant to which OncoC4 obtains a license from a Third Party under certain Licensed Patents or Licensed Know-How. Complete copies of the Upstream Agreements and any amendments or modifications thereto have been provided to BioNTech prior to the execution of this Agreement.

1.106. “**Valid Claim**” means [***].

1.107. “**VAT and Indirect Taxes**” means any value added, sales, purchase, turnover or consumption tax as may be applicable in any relevant jurisdiction.

1.108. “[***]” means, [***].

1.109. “[***] **Agreements**” means agreements between [***] and OncoC4 with respect to the Licensed Compound or Licensed Products, but not including the [***] License.

1.110. “[***] **License**” means [***].

1.111. Additional Definitions. The following terms have the respective meanings set forth in the Sections indicated below:

Definition	Section
392 Collaboration Termination	1.10
392 License Termination	1.10
[***] Guangzhou	1.2
Agreement	Preamble
AI-025 Inventions	8.1(d)
AI-025 Label License	2.1(a)
AI-061 Conditions	2.1(a)
AI License	1.10
Allegedly Breaching Party	13.3(a)
Alliance Manager	6.7(a)
Audited Site	4.1(f)
Auditor	7.8(a)
BioNTech	Preamble
BioNTech Development Plan	3.1(b)
BioNTech Foreground Invention	8.1(c)(i)
BioNTech Foreground Patents	8.1(c)(i)
BioNTech Indemnified Parties	11.1
BioNTech Product Invention	8.1(c)(ii)
BioNTech Product Patents	8.1(c)(ii)
Biosimilar Application	8.3(f)(i)
Breaching Party	13.3(a)
CAPA	4.1(f)
CDP	3.1(a)(i)
[***] License	Schedule 10.2(i)
Commercialization Plan	5.3(b)

Competing Program	2.6(b)
Completion of first Phase 1 Trial of AI-061	1.78
Covered Period	3.1(a)(i)
Development Milestone Event	7.4(a)
Development Milestone Payment	7.4(a)
DOJ	15.18
Effective Date	15.18
Enforcement or Defense Action	15.18
Excess Development Costs	3.2(b)
Exclusive License	2.1(a)
Execution Date	Preamble
First Indication	1.58
FTC	15.18
GOVERNMENT OFFICIAL	15.17(c)
HSR Act	15.18
Incremental Withholding	7.9(a)
Infringement Claim	8.4
IP Notice	8.3(a)
Joint Development Budget	3.1(a)(i)
***	8.1(b)(i)
***	8.1(b)(i)
JSC	6.1
Licensed Single Product	1.67
Mediation Period	Schedule 13.4(d)
***	10.2(l)
Mono/PD-1 Combinations	3.1(a)(i)
New Affiliate	2.6(b)
Non-Breaching Party	13.3(a)
OncoC4	Preamble
OncoC4 Indemnified Parties	11.2
***	10.2(p)
Option	2.2
Option Effective Date	2.2(b)
Option Exercise Fee	7.2
Option Exercise Notice	2.2(a)
*** License	Schedule 1.105

***] Settlement	Schedule 1.105
***]	2.7
Other Active	1.30
Other Combinations	3.1(b)
Party and Parties	Preamble
Party Vote	4.3
Patent Extension	8.2(d)
Pharmacovigilance Agreement	2.9
PROHIBITED CONDUCT	15.17(a)
Proviso Covenant	2.1(a)
Reduction Floor	7.7(f)
Representatives	9.1(b)
Reserved Financial Decision	6.5(a)(i)
Reserved Rights	2.5
Reversion Agreement	Schedule 13.4(d)
Reversion Products	13.4(b)
Royalty Term	7.5(b)
Rules	14.2
Sales Milestone Event	7.4(b)
Sales Milestone Payment	7.4(b)
Securitization Transaction	15.1(a)(ii)
Shared CDP Liability Claims	11.1
Subcommittee	6.6
Supply Agreement	5.1(a)
Technology Transfer	5.2(a)
Term	13.1
Terminated Product	13.4(e)
Terminated Product Agreement	13.4(e)
Third Party Action	11.1
Third Party Claim	11.3(a)
Withholding Action	7.9(a)

ARTICLE II
LICENSE GRANTS

2.1 License Grants.

(a) License Grant to BioNTech. Subject to the terms and conditions of this Agreement, OncoC4 hereby grants to BioNTech an exclusive (but not to the exclusion of OncoC4's Reserved Rights), non-transferable (except in accordance with Section 15.1), sublicensable (through multiple tiers, subject to Section 2.3), (i) royalty-bearing license under the Licensed Know-How, Licensed Patents, and [***], to Exploit Licensed Compounds and Licensed Products in the Field in the Territory and (ii) royalty-free license under any AI-025 Patents or any AI-025 Know-How, the Licensed Know-How, Licensed Patents, and [***], to Exploit AI-025 not co-formulated with ONC-392, but used in combination with ONC-392 (whether co-packaged, co-indicated, co-labeled or any other combined use) (for clarity, not including in AI-061 or AI-061 Products), (such license under clause (ii), the "**AI-025 Label License**") in the Field in the Territory (clause (i) and (ii), collectively, the "**Exclusive License**"). Notwithstanding the foregoing, (A) unless and until BioNTech exercises the Option in accordance with Section 2.2, despite the Exclusive License granted to BioNTech under this Section 2.1(a) with respect to AI-061, AI-061 Products and AI-025, BioNTech hereby covenants that its Exploitation of AI-061, AI-025 and AI-061 Products: (I) shall be limited to conducting Development and Manufacturing activities with respect to AI-061 or AI-061 Products solely in accordance with the CDP during the Option Period, and (II) shall not include the sale, offer for sale, distribution, promotion, marketing or other Commercialization of AI-061 or AI-061 Products (or any other Licensed Product containing AI-061) (the limitations described in clauses (I) and (II) are referred to herein as the "**AI-061 Conditions**"), and (B) in all instances BioNTech hereby covenants that its Exploitation of AI-025 shall not include the Exploitation of AI-025 other than within the context of and as part of AI-061 (the "**Proviso Covenant**"). The AI-061 Conditions shall no longer apply on or after the Option Effective Date in the event BioNTech exercises the Option. For the avoidance of doubt, unless otherwise agreed upon in writing by the Parties in the form of an amendment or restatement of this Agreement or a new license agreement, the rights granted to BioNTech with respect to AI-025 are limited to the AI-025 Label License, subject always to the Proviso Covenant, and Exploitation of AI-025 solely within the context of and as part of AI-061 or AI-061 Products (including the right to manufacture AI-025 in order to Exploit AI-061 or AI-061 Products as a Licensed Product), and under no circumstances will BioNTech or its Affiliates obtain any right or license to use AI-025 as a monotherapy or in combination with any other therapeutically active ingredient except as expressly contemplated hereby with respect to the AI-025 Label License, subject always to the Proviso Covenant, and the use of AI-025 solely within the context of and as part of AI-061 or AI-061 Products as a combination product. It is understood that for purposes of this Agreement, despite being a product that combines two (2) active ingredients, AI-061 and AI-061 Products are deemed to be a "Licensed Single Product" rather than a "Combination Product." However, BioNTech retains the right (unless it allows the Option to lapse without exercise) to include AI-061 or an AI-061 Product in a Combination Product, and if BioNTech Develops AI-061 or an AI-061 Product in a Combination Product with [***] or more Other Actives, in such case, AI-061 or such AI-061 Product shall be treated as the Licensed Product component of such Combination Product.

(b) License Grant to OncoC4. Subject to the terms and conditions of this Agreement, BioNTech hereby grants to OncoC4, a non-exclusive, non-transferable (except in accordance with Section 15.1), sublicensable (through multiple tiers) to subcontractors, only with BioNTech's prior written consent, except that such written consent will not be required for sublicenses to OncoC4's Affiliates, Service Providers or any subcontractors listed on Schedule 2.1(b), royalty-free license under the BioNTech Technology and [***] to carry out OncoC4's obligations under the CDP. For clarity, OncoC4 shall not be permitted to sublicense the entirety of its co-development obligations under the CDP to any Affiliate or Third Party.

2.2 AI-061 Option. OncoC4 hereby grants BioNTech the exclusive option (the "**Option**") exercisable during the Option Period to be released from its covenant as to the AI-061 Conditions restricting its practice of the Exclusive License with respect to AI-061 Products, including that BioNTech shall be released from its covenants not to exercise the right to sell, offer for sale, distribute, promote, market and otherwise Commercialize AI-061 (or any other Licensed Product containing AI-061). The Option shall be exercisable as follows:

(a) At any time during the Option Period, BioNTech may exercise the Option by delivery of written notification to OncoC4 of its decision to exercise the Option (the "**Option Exercise Notice**").

(b) Following the delivery of the Option Exercise Notice, BioNTech shall pay the Option Exercise Fee to OncoC4 as set forth in Section 7.2. Subject to BioNTech's compliance with this Section 2.2 and Section 7.2, the date on which OncoC4 receives the Option Exercise Fee will thereafter be the "**Option Effective Date**" hereunder.

(c) Effective upon the Option Effective Date, the AI-061 Conditions and BioNTech's covenants in Section 2.1(a) with respect thereto shall terminate and, subject to the terms and conditions of this Agreement, BioNTech shall have the right to practice its Exclusive License with respect to AI-061 and AI-061 Products under Section 2.1(a), and following the Option Effective Date and for the remainder of the Term AI-061 Products shall be considered a Licensed Product and a Mono/PD-1 Combination hereunder, all of the foregoing happening automatically and without the need for any further action by the Parties.

(d) Notwithstanding anything contained herein, effective upon the Option Effective Date and thereafter during the Term: (i) for any Development of AI-061 Products as a Mono/PD-1 Combination (i.e., not in combination with any other therapeutically active ingredient), the AI-061 Product shall be deemed to be a Licensed Single Product for purposes of calculating milestone payments and royalties under Sections 7.4 through 7.7; and (ii) if an AI-061 Product is included in a Combination Product that is not a Mono/PD-1 Combination (e.g., an AI-061 Product in combination with a therapeutically active ingredient that is not a PD-1 Product), such Licensed Product shall not trigger any Development Milestone Payments set forth in Section 7.4(a), but shall be eligible to trigger Sales Milestone Payments under Section 7.4(b) and OncoC4 shall be eligible to receive royalties for the sales of any such Licensed Product.

(e) If BioNTech does not exercise the Option prior to the expiration of the Option Period in accordance with Section 2.2 and Section 7.2, then (i) the AI-061 Conditions and BioNTech's covenant with respect thereto shall remain in effect, (ii) AI-025 shall be excluded

from the definition of Licensed Compound, and BioNTech will no longer have any option, license or right to AI-025 (including, for clarity, AI-025 included in AI-061 Products, but without otherwise limiting BioNTech's Exclusive License with respect to ONC-392 and Anti-CTLA-4 Antibodies) as of the date of the expiration of the Option Period, (iii) neither AI-061 nor any AI-061 Product will be a Licensed Product hereunder and BioNTech will no longer have the right to pursue AI-061 or AI-061 Products as a Licensed Product or as a Mono/PD-1 Combination hereunder for lack of rights to AI-025 provided that BioNTech shall still have its Exclusive License to ONC-392, including the right to exclude others from Exploiting ONC-392 as included in AI-061 or AI-061 Products, and (iv) all rights granted to BioNTech with respect to AI-025 (including, for clarity, rights to AI-025 included in AI-061 or AI-061 Products and the AI-025 Label License) shall terminate. [***]

2.3 Sublicensing of Rights by BioNTech.

(a) BioNTech Right to Sublicense. Subject to the requirements of Section 2.3(b), BioNTech will have the right to grant Sublicenses (through one or multiple tiers) of the rights granted to BioNTech pursuant to Section 2.1(a) to its Affiliates and Third Parties without the need in any case to obtain the prior written consent of OncoC4.

(b) Sublicense Requirements. Each Sublicense granted by BioNTech to a Third Party pursuant to Section 2.3(a) will be in writing and will be subject and subordinate to, and consistent with, the terms and conditions of this Agreement. No Sublicense will diminish, reduce or eliminate any obligation of either Party under this Agreement. BioNTech will be liable for any act or omission of any Sublicensee that is in breach of any of BioNTech's obligations under this Agreement as though the same were a breach by BioNTech, and OncoC4 will have the right to proceed directly against BioNTech without any obligation to first proceed against such Sublicensee. Each Sublicense will contain the following provisions: (i) a requirement that the Sublicensee comply with all applicable terms of this Agreement (including confidentiality and intellectual property provisions consistent with those set forth herein) and the Upstream Agreements, (ii) without limiting the foregoing, if such Sublicense contains a right to Commercialize any of the Licensed Products, such Sublicense will also contain the following provisions: (A) a requirement that the Sublicensee submit applicable reports to BioNTech to the extent necessary or relevant to allow BioNTech to prepare or keep the reports required to be made or records required to be maintained under this Agreement, and (B) a requirement that allows BioNTech to perform an audit of such Sublicensee consistent with the audit requirement set forth in Section 7.8, with the results thereof to be reportable to OncoC4. Any Sublicense granted hereunder that is inconsistent with this Section 2.3(b) will be null and void. [***]

2.4 Performance by Contractors. Each Party may contract or delegate any portion of its obligations hereunder to a Third Party contractor subject to Section 15.8; *provided*, that (i) the contractor undertakes in writing commercially reasonable obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties with respect to Confidential Information pursuant to ARTICLE IX hereof; and (ii) the contractor undertakes in writing to assign or exclusively license back (with the right to sublicense) all intellectual property with respect to the Licensed Compound or a Licensed Product developed in the course of performing any such work to the Party retaining such contractor. In addition, notwithstanding the foregoing, any such contracting or delegation by OncoC4 shall be only with BioNTech's advance, written consent, except with respect to any

OncoC4 Affiliate, Service Provider or subcontractor listed on Schedule 2.1(b); *provided*, that the performance by any Service Provider of activities involving a BioNTech Product hereunder shall be subject to the satisfactory completion of any customary and reasonable vendor qualification process requested by BioNTech and approved by the JSC.

2.5 Reservation of Rights. The Exclusive License and the rights granted under Section 2.1(a) are subject to the retained, non-exclusive right of OncoC4 and its Affiliates to use and practice the Licensed Know-How, Licensed Patents, [***] to perform its obligations under this Agreement and the Upstream Agreements (collectively, the “**Reserved Rights**”) and do not include any rights not expressly granted to BioNTech hereunder. No rights, other than those expressly set forth in this Agreement, are granted to either Party under this Agreement, and no additional rights beyond those expressly set forth herein will be deemed granted to either Party by implication, estoppel or otherwise, with respect to any intellectual property rights. All rights not expressly granted by either Party or its Affiliates to the other Party under this Agreement are reserved. Neither Party nor any of its Affiliates will use or practice any Know-How or Patents licensed or provided to such Party or any of its Affiliates under this Agreement outside the scope of or otherwise not in compliance with the rights and licenses granted to such Party and its Affiliates under this Agreement. For clarity, the Exclusive License and the rights granted under Section 2.1(a) shall not include any right or license under the Licensed Know-How or Licensed Patents to any Other Active which Other Active is Claimed by any Patent Controlled by OncoC4 and where such Claim applies to such Other Active independently of its inclusion in a Combination Product. If requested by either Party, the Parties will negotiate in good faith, either as a separate written agreement or an amendment to this Agreement, with respect to any other product Controlled by OncoC4 or its Affiliates that is used in combination with the Licensed Compound, if any. For further clarity, to the extent that a Licensed Patent is directed to the combination of a Licensed Compound or Licensed Product with an Other Active, the foregoing sentences are not intended to limit BioNTech’s rights to such Patent as it relates to such combination or BioNTech’s rights to Exploit such combination; *provided*, in each case, that BioNTech’s rights to Exploit such Other Active in such combination are derived independently of OncoC4, its Affiliates and the CDP. Moreover, it is understood that for any Patents that are Controlled by OncoC4 or its Affiliate that Claim combination therapies or protocols that include a Licensed Compound or Licensed Product, such Patents are included in the Licensed Patents (subject to this Section 2.5) and nothing in this Section is intended to prevent BioNTech from Developing or Commercializing any Licensed Product for or with a label for use in such combination; *provided*, in each case, that any rights BioNTech or its Affiliate have or may need to Exploit the other product(s) in such combination (i.e., other than a Licensed Compound or Licensed Product) are derived independently of OncoC4, its Affiliates and this Agreement.

2.6 Exclusivity.

(a) Obligations. Other than in the performance of activities under this Agreement, during the period commencing on the Execution Date and ending on the date of the First Commercial Sale of the first Licensed Product in any country in the Territory: (i) OncoC4 shall collaborate exclusively with BioNTech for the Development, Manufacturing and Commercialization of Licensed Products; and (ii) OncoC4 shall not (and will not permit its Affiliates to and hereby covenants that they shall not), Exploit, either alone or directly or indirectly with any Third Party, collaborate with, enter into an arrangement with, work for the benefit of, grant any license to (or assign, sell or transfer rights to) or otherwise knowingly

enable any Third Party to Exploit, any Anti-CTLA-4 Antibody, or any product with a mechanism of action that is the same as an Anti-CTLA-4 Antibody. It is understood that such product may have one or more additional mechanisms of action, in addition to that of an Anti-CTLA-4 Antibody, such as but not limited to the cases of a protein with multiple targeting moieties and/or with a targeting moiety and a payload. For the avoidance of doubt, the exclusivity covenants set forth in this Section 2.6(a) shall not apply to CD80/CD86 Compounds, and nothing contained in this Section 2.6 shall prohibit, limit or otherwise restrict OncoC4 or its Affiliates from Exploiting CD80/CD86 Compounds during or following the Term.

(b) Exceptions. Notwithstanding Section 2.6(a), if a Third Party becomes an Affiliate of OncoC4 through merger, acquisition, consolidation or other similar transaction (a “**New Affiliate**”) and such New Affiliate, as of the effective date of such transaction, is engaged in Exploitation activities that, if conducted by OncoC4, would be in breach of its exclusivity obligations set forth in Section 2.6(a) (such Exploitation activities, a “**Competing Program**”) then:

(i) If such transaction results in a Change of Control of OncoC4, then such New Affiliate shall have the right to continue such Competing Program and such continuation shall not constitute a breach by OncoC4 of its exclusivity obligations set forth in Section 2.6(a); provided, that (A) such New Affiliate conducts such Competing Program independently of the activities under this Agreement and does not use any Licensed Know-How, [***], BioNTech Technology or any Confidential Information of BioNTech in the conduct of such Competing Program; (B) OncoC4 and such New Affiliate institute commercially reasonable technical and administrative procedures and safeguards designed to ensure that the requirements set forth in the foregoing clause (A) are met, including by creating “firewalls” between (X) the personnel working under such Competing Program and (Y) the personnel working on activities under the CDP; provided, further, that senior management personnel may review and evaluate plans and information regarding the research, development and commercialization of such Competing Program in connection with product portfolio decision-making, but shall not disclose information regarding Development, Commercialization, or any Licensed Product under this Agreement to the personnel directly working on the Competing Program; and (C) OncoC4 shall continue to co-fund Development under the CDP, but (1) the JSC shall disband, (2) BioNTech shall only be required to provide an annual, high level summary report as to its Development program hereunder but shall not be required to provide interim (quarterly) reporting nor information as to its future plans, (3) OncoC4 shall not have the right or any obligation (subject to a reasonable transition period to be mutually agreed upon by the Parties) to conduct any further Development of Licensed Products, (4) the license granted to OncoC4 under Section 2.1(b) shall terminate; and (5) BioNTech shall have sole discretion over changes to the CDP; provided, that OncoC4 shall retain its rights under Section 7.8, [***]. Notwithstanding the foregoing, in the event such New Affiliate does not intend to continue such Competing Program (including if such New Affiliate is required under applicable competition Laws to divest or wind down the Competing Program), the Parties shall discuss in good faith and mutually agree on procedures and safeguards to implement during a reasonable period (not to exceed [***] months or a shorter period prescribed by Law, if applicable) following the closing of such Change of Control during which such New Affiliate may divest or wind down the Competing Program as promptly as practicable, such divestment or wind down shall not constitute a breach by OncoC4 of its exclusivity obligations set forth in Section 2.6(a), and clauses (1) through (5) above shall not apply assuming such procedures and safeguards are implemented and such divestment or

wind down is completed within the mutually agreed period, not to exceed [***] months or a shorter period if prescribed by Law, if applicable, following the closing of such Change of Control. Notwithstanding the foregoing, if BioNTech exercises the Option in accordance with Section 2.2 and this Section 2.6(b)(i) comes into effect, the Parties and the New Affiliate shall discuss in good faith and mutually agree on commercially reasonable terms and conditions to govern their ongoing interactions with respect to ONC-392, AI-025 and AI-061, which terms and conditions shall provide for, at a minimum, the sharing of information between the Parties as required by applicable Law and such other matters as may be necessary for each Party and their Affiliates to comply with applicable Laws.

(ii) If such transaction does *not* result in a Change of Control of OncoC4, then OncoC4 and its New Affiliate shall have [***] months from the closing date of such transaction to wind down (or otherwise cease or suspend all Exploitation activities) or divest such Competing Program, and its New Affiliate's conduct of such Competing Program during such [***] month period shall not constitute a breach by OncoC4 of its exclusivity obligations set forth in Section 2.6(a); *provided*, [***].

(c) **BioNTech Competitors.** Notwithstanding Section 2.6(a), if a Third Party becomes a New Affiliate of OncoC4 and such New Affiliate is a BioNTech Competitor, then, regardless of whether the New Affiliate is engaged in any Competing Program: (A) such New Affiliate shall not use any Licensed Know-How, [***], BioNTech Technology or any Confidential Information of BioNTech in the conduct of its business or activities; (B) OncoC4 and such New Affiliate shall institute commercially reasonable technical and administrative procedures and safeguards designed to ensure that the requirements set forth in the foregoing clause (A) are met, including by creating "firewalls" between (X) the personnel working under any activities of the New Affiliate and (Y) the personnel working on activities under the CDP; *provided, further*, that senior management personnel may review and evaluate plans and information regarding the business activities of the New Affiliate in connection with product portfolio decision-making, but shall not disclose information regarding Development, Commercialization, or any Licensed Product under this Agreement to the personnel directly working for the New Affiliate's activities; and (C) OncoC4 shall continue to co-fund Development under the CDP, but (1) the JSC shall disband, (2) BioNTech shall only be required to provide an annual, high level summary report as to its Development program hereunder but shall not be required to provide interim (quarterly) reporting nor information as to its future plans, (3) OncoC4 shall not have the right or obligation (subject to a reasonable transition period to be mutually agreed upon by the Parties) to conduct any further Development of Licensed Products, (4) the license granted to OncoC4 under Section 2.1(b) shall terminate; and (5) BioNTech shall have sole discretion over changes to the CDP; *provided*, that OncoC4 shall retain its rights under Section 7.8, and; *provided, further*, that OncoC4's co-funding commitment shall not exceed its co-funding obligations as set forth in the last CDP and Joint Development Budget approved by the JSC in accordance with this Agreement (but not pursuant to an exercise by BioNTech of its final decision-making authority after becoming aware of a proposed transaction involving OncoC4 and a BioNTech Competitor) in effect prior to the closing of the effective date of the transaction contemplated under this Section 2.6(c), and BioNTech's right to amend the CDP shall not include the right to impose additional co-funding or any other obligations on OncoC4. Notwithstanding the foregoing, if BioNTech exercises the Option in accordance with Section 2.2 and this Section 2.6(c) comes into effect, the Parties and the New Affiliate shall discuss in good faith and mutually agree on commercially reasonable terms and conditions to

govern their ongoing interactions with respect to ONC-392, AI-025 and AI-061, which terms and conditions shall provide for, at a minimum, the sharing of information between the Parties as required by applicable Law and such other matters as may be necessary for each Party and their Affiliates to comply with applicable Laws.

2.7 Upstream Agreements and AI Agreements. If any rights granted to BioNTech under this Agreement are Controlled by OncoC4 pursuant to an Upstream Agreement, [***]. Unless otherwise expressly agreed by the Parties in writing, OncoC4 shall be solely responsible for any payments due to the Third Party licensors under any Upstream Agreement as a result of any sublicense granted to BioNTech hereunder and BioNTech's or its Affiliate's or a Sublicensee's exercise of such sublicense in accordance with the terms therein and herein. Except as otherwise mutually agreed by the Parties in writing or contemplated by this Agreement, OncoC4 shall timely perform its obligations under each of the Upstream Agreements in all material respects and maintain them in full force and effect during the Term (subject to the expiration provisions of each Upstream Agreement), including timely payment of all amounts due to be paid by OncoC4 thereunder. Except as otherwise mutually agreed by the Parties in writing or contemplated by this Agreement, OncoC4 shall not amend any Upstream Agreement or the AI Agreements during the Term in a manner that would or would reasonably be expected to adversely affect BioNTech in any material respect without BioNTech's advance, written consent. [***] In accordance with the provisions of the [***] License, a copy of the [***] License is attached hereto as Schedule 2.7. As soon as reasonably practicable following the Effective Date (or the date of the joint press release contemplated by Section 9.2(a), if earlier), OncoC4 shall be permitted to disclose this Agreement and BioNTech's identity with respect to this Agreement to [***], and OncoC4 shall use Commercially Reasonable Efforts to obtain a written waiver or amendment of the [***] License to clarify that BioNTech is not subject to the sublicensing requirements under the [***] License.

2.8 BioNTech Agreements. Unless otherwise mutually agreed by the Parties in writing, and notwithstanding anything contained herein, BioNTech shall be solely responsible for any payments due to Third Parties (a) in respect of BioNTech Products or Other Actives Controlled by Third Parties, or (b) as a result of any sublicense granted to OncoC4 hereunder and OncoC4's exercise of such sublicense in accordance with the terms hereof, except to the extent otherwise mutually agreed by the Parties in writing and provided in the CDP and Joint Development Budget.

2.9 Transfer of Licensed Know-How. As promptly as reasonably practicable after the Effective Date, OncoC4 will use Commercially Reasonable Efforts to disclose and make available to BioNTech copies or other tangible embodiments of the Licensed Know-How that exists as of the Effective Date, including transfers of the items of Licensed Know-How in the scope and forms or formats and on the timelines to be agreed upon by the Parties within [***] days following the Effective Date. During the Term, OncoC4 will use reasonable efforts to respond to any reasonable requests by BioNTech for additional Licensed Know-How that is Controlled by OncoC4 and relates to the Development and Manufacture of the Licensed Compound or and Licensed Products, in the form such Licensed Know-How is maintained by OncoC4 or as otherwise mutually agreed by the Parties. OncoC4 shall, upon or promptly following the Effective Date, provide to BioNTech a copy of the "data room" made available to BioNTech that OncoC4 established for BioNTech's review during the negotiation of this Agreement, including its index and all of its contents as of the Effective Date, in an electronic

format reasonably agreed upon by the Parties; *provided*, that such format shall be a format supported by OncoC4's "data room" vendor and shall allow for downloading (if such format is online), copying and printing (for clarity, it is agreed and acknowledged that such copy of the "data room" shall not include the [***] Agreement).

ARTICLE III DEVELOPMENT

3.1 Development Diligence; Development Responsibilities.

(a) Joint Development.

(i) Joint Clinical Development Plan. OncoC4 and BioNTech shall use Commercially Reasonable Efforts to conduct Development activities with respect to the Licensed Compound and Licensed Products, either as a monotherapy or in combination solely with a PD-1 Product (collectively, the "**Mono/PD-1 Combinations**"), in each case, in accordance with a joint clinical development plan (the "**CDP**") approved by the JSC in accordance with the terms of this Agreement. The CDP shall include the following items for the remainder of the then-current Calendar Year and the following Calendar Year (each, a "**Covered Period**"): (i) the proposed overall program of Development of Licensed Products in Mono/PD-1 Combinations, including Clinical Trials, and regulatory plans and other elements of obtaining Regulatory Approvals of such Licensed Products in the Field in the Territory, including Development activities for AI-061 until Completion of the first Phase 1 Trial of AI-061 (and if BioNTech exercises the Option, additional Development activities for AI-061, including regulatory plans and other elements of obtaining Regulatory Approval for AI-061); (ii) the anticipated start dates and data availability dates of such Clinical Trials, and anticipated timelines and strategies for filing of applications for Regulatory Approvals in the Territory; (iii) the respective roles and responsibilities of each Party in connection with such joint Development activities (including sponsorship of Clinical Trials); (iv) a detailed budget for all such joint Development (including Manufacturing) activities in the Field in the Territory for the Covered Period (the "**Joint Development Budget**"), and (v) such other items as may be approved by the JSC. An initial draft of the CDP and estimates for the Joint Development Budget are set forth on Schedule 3.1(a) attached hereto; *provided*, that the Parties agree and acknowledge that a complete CDP including all elements described above will be negotiated in good faith and approved by the JSC as promptly as practicable (but not more than [***] days) following the Effective Date; *provided, further*, that except to the extent otherwise approved by the JSC, such complete CDP shall be consistent with the initial draft CDP set forth on Schedule 3.1(a) in all material respects.

(ii) Amendments to the CDP. On an annual basis no later than [***] of each Calendar Year, or by such date or more often as the Parties mutually agree, the Parties shall, through the JSC, prepare amendments to the then-current CDP including a proposed CDP and Joint Development Budget for the immediately following Covered Period, and which amendments shall be finalized, approved, and included into such CDP by the JSC, no later than [***] of each Calendar Year for the next Calendar Year. Each such amended CDP shall specify the items described in Section 3.1(a). Such amended Joint Development Budget shall reflect the Parties' good faith estimate of the costs of the activities set forth in the CDP and include an updated rolling budget for the Development activities to be performed during the relevant Covered Period (broken down by Calendar Quarter under the CDP), and a forecast of the

anticipated Joint Development Budgets for each subsequent Calendar Year thereafter through completion of all Development activities set forth in such CDP. Such updated and amended CDP shall reflect any changes (including any transfer of sponsorship of any Clinical Trials to be effected in accordance with this Agreement), re-prioritization of studies within, reallocation of resources with respect to, or additions to, respectively, the then-current CDP and Joint Development Budget. Once approved by the JSC, the amended CDP (including the corresponding amended Joint Development Budget) shall become effective for the applicable period on the date approved by the JSC (or such other date as the JSC shall specify). Any such approved amended CDP (including the corresponding amended Joint Development Budget) shall supersede, respectively, the previous CDP and Joint Development Budget.

(b) **BioNTech Development.** BioNTech shall have the right (directly, or through its Affiliates and Sublicensees), and shall be solely responsible for all Development activities for the Licensed Compound and Licensed Products in any other form or combination other than the Mono/PD-1 Combinations (collectively, “**Other Combinations**”), at its own expense, and in accordance with a research and development plan at a summary level of detail (the “**BioNTech Development Plan**”) prepared by BioNTech and shared with OncoC4 through the JSC. BioNTech shall use Commercially Reasonable Efforts to Develop a Licensed Product in at least one (1) Indication for an Other Combination. Without limiting BioNTech’s obligations set forth above in this Section 3.1(b), within [***] days following the Effective Date, and within [***] days following January 1 of each Calendar Year during the Term, BioNTech shall provide the JSC with a (i) then-current BioNTech Development Plan that summarizes the major research and Development activities reasonably anticipated to be undertaken by or on behalf of BioNTech with respect to the Licensed Compound and Licensed Products outside the CDP and Joint Development Program and (ii) commencing in the Calendar Year following BioNTech’s initial delivery of the BioNTech Development Plan, an annual summary update with respect to its Development activities taken during the prior Calendar Year, which may consist of a PowerPoint presentation or other written elements which would then be shared with all JSC members. BioNTech may update the BioNTech Development Plan at its discretion; *provided*, that BioNTech shall promptly notify OncoC4 or the JSC of any material adverse changes to the BioNTech Development Plan or the activities thereunder (e.g., a decision to cease Development of a Licensed Product or Indication). BioNTech shall also include in each BioNTech Development Plan any Development of Mono/PD-1 Combinations that it plans to conduct or has conducted outside the Joint Development Program; *provided*, that, subject to the terms of any written agreement between BioNTech and a Third Party in respect of the PD-1 component of such Mono/PD-1 Combinations (a “**BNT PD-1 License**”), BioNTech shall first offer to OncoC4 in good faith, by delivery of written notice, the opportunity for OncoC4 to co-fund any and all Development of Mono/PD-1 Combinations under an amended CDP (which offer shall remain open for at least [***] days following BioNTech’s written notice, and during such period the Parties shall discuss in good faith the possibility of adding such Mono/PD-1 Combination to the CDP and BioNTech shall provide or cause to be provided to OncoC4 such information as OncoC4 may reasonably request within the first [***] days following BioNTech’s written notice (*provided*, that such [***] day period shall not limit the obligation of the Parties to discuss relevant matters in good faith during such [***] day period or prevent OncoC4 from asking reasonable follow-up questions) in respect of such Mono/PD-1 Combination), in each case, prior to pursuing such Development independently or with a Third Party and in accordance with all applicable confidentiality obligations and restrictions hereunder. In the event that as of the date of such written notice to OncoC4, there is a BNT PD-1 License, then, subject to any

confidentiality obligations to such Third Party, BioNTech will include in its written notice reasonable information pertaining to such BNT PD-1 License, in order for OncoC4 to evaluate whether or not to elect to co-fund any or all Development of the Mono/PD-1 Combinations. Notwithstanding any other provision of this Agreement, if the terms of a BNT PD-1 License prevent OncoC4 from co-funding the Development of a Mono/PD-1 Combination under an amended CDP, and because of such BNT PD-1 License such Development is not conducted under the CDP, the Parties shall discuss in good faith appropriate amendments to Section 7.4(a) so that OncoC4 is not prevented from earning an equitable portion of any Development Milestone Payment(s) as a result of such BNT PD-1 License.

(c) Development Responsibilities. Each Party will conduct its Development activities under this Agreement and the CDP in good scientific manner and in compliance with all applicable Laws, including GLP and GCP, as applicable, current standards for pharmacovigilance practice, and all applicable requirements relating to the protection of human subjects.

3.2 Development Costs.

(a) Joint Development Costs. Except as otherwise provided in this Section 3.2, all Joint Development Costs incurred in accordance with the CDP and Joint Development Budget shall be shared equally (50/50) between BioNTech and OncoC4 in accordance with Section 7.3.

(b) Excess Development Costs. Each Party shall promptly inform the JSC in writing upon such Party determining that it has incurred or is likely to incur Joint Development Costs for a Calendar Year that exceed the portion of the Joint Development Costs allocated to such Party in the Joint Development Budget for such Calendar Year (“**Excess Development Costs**”). To the extent such Excess Development Costs fall under the definition of “Joint Development Costs,” they shall be treated as Joint Development Costs hereunder and shared equally (50/50) between the Parties. In the event either Party identifies Excess Development Costs, the Parties shall discuss in good faith through the JSC the Joint Development Costs that are necessary and reasonable in order to perform the activities set forth in the CDP and any proposed amendments to the Joint Development Budget.

(c) AI-061 Costs. Notwithstanding anything contained herein or in the CDP or Joint Development Budget, BioNTech’s share of Joint Development Costs for the first Phase 1 Trial of AI-061 shall not exceed [***] unless otherwise mutually agreed by the Parties through the JSC; *provided*, that OncoC4 may elect to fund Joint Development Costs for AI-061 incurred in accordance with the CDP that BioNTech is not responsible for as a result of this Section 3.2(c) and the Parties shall continue to conduct the activities with respect to AI-061 set forth in the CDP. For clarity, OncoC4 shall have no obligation to fund any such additional Joint Development Costs for AI-061, and if OncoC4 does not elect to fund such additional Joint Development Costs for AI-061, the Parties shall promptly wind down and terminate Development activities in support of AI-061.

(d) BioNTech Development Costs. BioNTech shall be solely responsible for (i) all Development costs incurred by or on behalf of BioNTech in respect of Other Combinations and BioNTech Products; (ii) BioNTech’s share of Joint Development Costs

incurred in accordance with this Agreement and the CDP; and (iii) all costs incurred by or on behalf of BioNTech in respect of Development outside the Joint Development Program and CDP. Nothing in this Agreement shall be read to prevent BioNTech (and those deriving rights from BioNTech) from Developing any Mono/PD-1 Combinations outside the Joint Development Program and CDP (provided that prior to doing so, in accordance with Section 3.1(b), BioNTech will offer to OncoC4 the opportunity the co-fund the applicable Development under the Joint Development Program).

(e) Covenant of OncoC4. At all times prior to the completion of the activities contemplated by the CDP, OncoC4 and its Affiliates, collectively, shall maintain sufficient cash reserves, liquid assets, or other sources of immediately available funds (in each case, with reputable financial institutions selected by OncoC4 in accordance with industry practice and the exercise of its reasonable business judgment), as reasonably necessary for OncoC4 to fund its share of Joint Development Costs during the following [***] months as such Joint Development Costs are anticipated in a then-current, Joint Development Budget approved by the JSC; *provided*, that (i) OncoC4 shall have at least [***] months following approval of a new Joint Development Budget or material amendment thereto to acquire such reserves, assets or funds and (ii) upon BioNTech's reasonable request (not more than once per Calendar Year absent OncoC4's failure to comply with this Section 3.2(e) or make an undisputed payment under this Agreement or the CDP), OncoC4 shall provide BioNTech with reasonable documentary evidence reasonably satisfactory to BioNTech (acting in good faith) of its compliance with this Section 3.2(e). Without limiting the foregoing, upon BioNTech's reasonable request (not more than once per Calendar Year without cause), OncoC4 shall disclose to BioNTech the financial institution(s) that hold the assets of OncoC4 and its Affiliates that satisfy the conditions of this Section 3.2(e). BioNTech may comment on such financial institutions and OncoC4 will in good faith take into account and consider BioNTech's reasonable and timely suggestions regarding OncoC4's choice of financial institution(s). For the avoidance of doubt, nothing in this Section 3.2(e) shall require OncoC4 or any of its Affiliates to maintain segregated accounts or restricted cash in order to satisfy its obligations hereunder. If OncoC4 is ever not in compliance with this covenant, OncoC4 shall promptly notify BioNTech in writing.

(f) Certain Development Costs Related to AI-025. If (i) BioNTech exercises the Option, (ii) the first product containing AI-025 to receive Regulatory Approval in any Major Market is AI-061, and (iii) a Combination Product Controlled by OncoC4 containing AI-025 and one (1) or more Other Actives subsequently receives Regulatory Approval in the same Major Market, then, only in the case of (i), (ii) and (iii), BioNTech may deduct from the royalties payable to OncoC4 under Section 7.5 with respect to AI-061 an amount equal to [***] of all Joint Development Costs incurred by BioNTech to Develop AI-061 for the Indication subject of such first Regulatory Approval of AI-061 up to the date of such first Regulatory Approval of AI-061.

3.3 Development Records and Reporting.

(a) Records. Each Party shall maintain complete and accurate records of all work conducted by or on behalf of such Party in furtherance of seeking Regulatory Approval for Licensed Products in the Field in the Territory. Such records will be maintained in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and in accordance with applicable Laws.

(b) **Reporting.** Each Party shall periodically provide to the JSC, on a Calendar Quarter basis or more frequently as reasonably requested by the JSC, an update regarding Development activities conducted by or on behalf of such Party with respect to each Licensed Product under the then-current CDP. In addition, each Party shall promptly share with the other Party all material developments and information that it comes to possess relating to the Development or Manufacturing of any Licensed Products and all other data and information that either Party may reasonably request to support the filing of Regulatory Materials in a mutually agreed format, including, without limitation, (i) safety concerns and adverse event reports for Licensed Products, and (ii) study reports and data generated from Clinical Trials of such Licensed Products. Without limiting the generality of the foregoing, each Party shall promptly report to the other Party in writing material developments which are reasonably expected to be materially detrimental to Development, including manufacturing failures.

(c) **Clinical Trial Reporting.** Each Party agrees that (i) each Clinical Trial conducted pursuant to the CDP or the BioNTech Development Plan that is required to be posted pursuant to applicable Law or applicable industry codes, including the PhRMA Code, on clinicaltrials.gov or any other similar registry shall be so posted, and (ii) all results of such Clinical Trials that are necessary for obtaining a Regulatory Approval for a Licensed Product in the Territory shall be posted on clinicalstudyresults.org and on any other registry with requirements consistent with the registration and publication guidelines of the International Committee of Medical Journal Editors, to the extent required. All data and information posted on clinicaltrials.gov, clinicalstudyresults.org or any other registry pursuant to this Section 3.3(c) shall be subject to prior review and authorization (subject to requirements of applicable Law), pursuant to Sections 9.2(c) and 9.2(e).

3.4 **Data Exchange.** In addition to its adverse event and safety data reporting obligations set forth in Section 4.3, each Party shall promptly provide the other Party with copies of all data and results and all supporting documentation (e.g., protocols, Investigator's Brochures, case report forms, analysis plans) Controlled by such Party that are generated by or on behalf of such Party or its Affiliates, Service Provider, Sublicensees, or contractors, if applicable, in the Development of Licensed Products in the Joint Development Program. For such items arising outside the Joint Development Program (i.e., in BioNTech's independent development not governed by the CDP), the JSC shall discuss in good faith the information to be provided to OncoC4, if any, beyond the required reporting under Section 4.3 to support OncoC4's activities under the CDP; *provided*, that in all events, BioNTech shall provide to OncoC4 such items as may be necessary or reasonably advisable for OncoC4 or its Affiliates or sublicensees to satisfy regulatory or other legal requirements.

ARTICLE IV REGULATORY MATTERS

4.1 **Regulatory Submissions and Approvals.**

(a) **Regulatory Responsibilities.** BioNTech will be responsible for all regulatory activities relating to the Licensed Products, including preparing and filing all MAAs and seeking all Regulatory Approvals for the Licensed Products in the Field in the Territory in accordance with the CDP or BioNTech Development Plan, as applicable, except for any

regulatory activities that are expressly delegated or transferred to OncoC4 in the CDP, as approved by the JSC, or as expressly set forth in this Agreement.

(b) Sponsorship of Clinical Trials and Ownership of Regulatory Materials. As between the Parties, unless otherwise agreed between the Parties through the JSC, OncoC4 shall (i) be the sponsor for Clinical Trials of Licensed Products that are Mono/PD-1 Combinations that are conducted under the CDP; and (ii) own all Regulatory Materials, including INDs and all submissions for the Clinical Trials under subclause (i). Notwithstanding the foregoing, (A) upon BioNTech's reasonable request, which request may be made any time following the first anniversary of the Effective Date, and the JSC's good faith discussion, OncoC4 shall transfer or cause to be transferred to BioNTech as promptly as practicable in accordance with applicable Law, sponsorship of any such Clinical Trial for which OncoC4 is the sponsor under the CDP, including any Regulatory Materials related thereto, as so approved by the JSC (for clarity, subject to Section 6.5(a)); and (B) if such sponsorship and Regulatory Materials have not already been transferred to BioNTech pursuant to subclause (A), six (6) months prior to the planned MAA submission for Regulatory Approval of a Licensed Product in a particular Indication, OncoC4 shall transfer or cause to be transferred to BioNTech as promptly as practicable in accordance with applicable Law, sponsorship of any Clinical Trial for which OncoC4 is the sponsor under the CDP (and transfer or make available to the extent not previously delivered or made available) all Regulatory Materials (including but limited to, the INDs) for the applicable Licensed Product. In each case (A) and (B), the Parties shall cooperate to submit such notifications and any other documents or instruments required by the applicable Regulatory Authority to effect the transfer of such sponsorship Regulatory Materials, as applicable. Furthermore, notwithstanding the foregoing, BioNTech will be the sponsor for and will own all Regulatory Materials, including all INDs and submissions for any Clinical Trials (1) conducted under the BioNTech Development Plan, or (2) set forth in the CDP or otherwise approved by the JSC for BioNTech to be the sponsor of, and any Regulatory Approval for the Licensed Products in the Field in the Territory. For the avoidance of doubt, any transfer of sponsorship of a Clinical Trial contemplated hereby shall be conducted under the oversight of the JSC in accordance with ARTICLE VI.

(c) Delegation or Transfer of Responsibilities for Clinical Trials. In the event that BioNTech has exercised its right under this Agreement to transfer sponsorship of any Clinical Trial(s) for which OncoC4 was originally the sponsor under the CDP to BioNTech and the JSC has approved such transfer in accordance with this Agreement (for clarity, subject to Section 6.5(a)), BioNTech may, notwithstanding the transfer of sponsorship thereof, delegate or transfer all or part of its responsibilities with respect to such Clinical Trial to OncoC4, in each case, as discussed and approved by the JSC in accordance with this Agreement (for clarity, subject to Section 6.5(a)), and in such instance the Parties shall promptly enter into an agreement delegating such responsibility in accordance with 21 C.F.R. §312.52, or any equivalent requirement in other jurisdictions or countries outside of the U.S., and shall cooperate to submit any such other notifications or other documents or instruments required by the applicable Regulatory Authority to effect such transfer or delegation of responsibilities.

(d) Right of Reference. Each Party hereby grants to the other Party, and such other Party's Affiliates and Sublicensees, a right to cross-reference or incorporate by reference any Regulatory Materials and any Regulatory Approval Controlled by such Party for any Licensed Product, and all data and other Know-How included or referenced therein or filed in

support thereof, subject to the scope of the licenses granted under Section 2.1, for the purpose of the other Party, its Affiliates or any Sublicensee conducting its or their designated regulatory activities, including, where applicable, applying for Clinical Trials and, in BioNTech's case, seeking or maintaining Regulatory Approvals, in each case, for Licensed Products in the Field in the Territory as permitted under this Agreement and to otherwise enable such Party to fulfill its obligations or in the case of BioNTech exercise its rights hereunder with respect to Licensed Products in the Territory. Notwithstanding anything express or implied in the foregoing, BioNTech grants no right to cross-reference or incorporate by reference any Regulatory Materials to the extent specifically pertaining to any BioNTech Product included in a Combination Product, and unless otherwise mutually agreed by the Parties, OncoC4 shall have no right to apply for any Regulatory Approval for any Licensed Product anywhere in the world.

(e) Regulatory Cooperation. Each Party will share with the other Party any existing or new regulatory information Controlled by such Party (including in relation to any INDs with respect to any Licensed Product) generated or received from Regulatory Authorities with respect to the Development of the Licensed Compound and Licensed Products, and each Party shall reasonably cooperate and support the other Party in all regulatory activities related to the Licensed Compound and Licensed Products in the Field in the Territory. Without limiting the foregoing:

(i) With respect to any Clinical Trial for Licensed Products in any Mono/PD-1 Combination which either (A) OncoC4 Controls and is the sponsor, or (B) BioNTech is the sponsor but has delegated or transferred all or part of its responsibilities with respect to such Clinical Trial to OncoC4, (I) OncoC4 shall promptly share with BioNTech all material information and all written correspondence received by OncoC4 or its Affiliate from a Regulatory Authority (or that otherwise is in OncoC4's possession or control and for which OncoC4 is not prohibited from sharing with BioNTech pursuant to any agreement with a Third Party) relating to such Clinical Trial, and (II) BioNTech shall have the right to review, comment, amend and approve (not to be unreasonably withheld, conditioned or delayed with respect to any Clinical Trial for which OncoC4 is the sponsor) any submissions or correspondence relating to such Clinical Trial prior to OncoC4 filing with relevant Regulatory Authorities (provided, that with respect to any Clinical Trial for which OncoC4 is the sponsor, OncoC4 will have final decision-making authority with respect to such submissions or correspondence to the extent required by applicable Law or to comply with applicable Law, and nothing contained herein will prevent OncoC4 from making any submission that is necessary in order to comply with applicable Law), and, to the extent permitted by applicable Law and Regulatory Authorities, BioNTech shall have the right but not the obligation to attend all meetings or calls with such Regulatory Authority.

(ii) BioNTech shall keep the JSC and OncoC4 reasonably informed of any material regulatory activities, communications and correspondences with a Regulatory Authority, and shall provide OncoC4 opportunities to review and comment on material regulatory submissions or correspondences, in each case, relating to any Licensed Compound or any Licensed Product, subject to OncoC4's compliance with its confidentiality obligations or restrictions. BioNTech shall consider OncoC4's timely comments thereon in good faith. In relation to meetings regarding Mono/PD-1 Combinations BioNTech will provide OncoC4 with reasonable advance notice of any scheduled meeting with any Regulatory Authority relating to regulatory matters for the Licensed Compound or any Licensed Product, and, to the extent

permitted by applicable Law and Regulatory Authorities, OncoC4 shall have the right but not the obligation to attend any meetings or call with such Regulatory Authority as an observer.

(f) Health Authority Inspections. The Parties will cooperate in good faith with respect to Regulatory Authority inspections of any site or facility where Clinical Trials or Manufacturing of the Licensed Compound or Licensed Products are conducted pursuant to this Agreement (each an “**Audited Site**”). Subject to applicable Law, OncoC4 will be given a reasonable opportunity to attend any inspection by any Regulatory Authority of the Audited Sites, and the summary or wrap-up meeting with a Regulatory Authority at the conclusion of such inspection. In the event that any Audited Site is found to be non-compliant with one or more of GLP, GCP, GMP or current standards for pharmacovigilance practice, BioNTech will submit to the JSC a proposed recovery plan or Corrective and Preventative Actions (“**CAPA**”) plan as soon as reasonably practicable after BioNTech, its Affiliates or Sublicensees or their permitted contractor receives notification of such non-compliance from the relevant Regulatory Authority and BioNTech will use reasonable efforts to implement such recovery plan or CAPA promptly after submission. BioNTech agrees, to the maximum extent reasonably possible, to include in any contract or other written arrangement with its permitted contractors a clause permitting OncoC4 to exercise its rights under this Section 4.1(f).

4.2 Recalls, Suspensions, and Withdrawals. Each Party shall promptly notify the other Party (but in no event later than [***]) following its determination that any event, incident or circumstance has occurred that may result in the need for a recall, market suspension or market withdrawal of a Licensed Product and shall include in such notice the reasoning behind such determination and any supporting facts. As between the Parties, BioNTech shall have the final decision-making authority to make the final determination whether to voluntarily implement any such recall, market suspension or market withdrawal during the Term; *provided*, that prior to any implementation of such a recall, market suspension or market withdrawal, BioNTech shall consult with OncoC4 and shall consider OncoC4’s comments in good faith. If a recall, market suspension or market withdrawal of a Licensed Product is mandated by a Regulatory Authority, as between the Parties, BioNTech shall initiate such a recall, market suspension or market withdrawal in compliance with applicable Law. BioNTech shall be responsible for all costs of any such recall, market suspension, or market withdrawal, except in the event and to the extent that a recall, market suspension or market withdrawal resulted from OncoC4’s material breach of its obligations hereunder or from OncoC4’s or its Representatives fraud, gross negligence or willful misconduct, in which case OncoC4 shall bear its proportionate share of the expense of such recall, market suspension or market withdrawal.

4.3 Pharmacovigilance. Within [***] days after the Effective Date and prior to commencement of any Clinical Trial for a BioNTech Product, the Parties will negotiate in good faith and finalize the actions that the Parties will employ with respect to Licensed Products to protect patients and promote their well-being in a written pharmacovigilance agreement in customary form and substance mutually agreed by the Parties and consistent with this Agreement (the “**Pharmacovigilance Agreement**”). The Pharmacovigilance Agreement shall delineate the Parties’ responsibilities with respect to pharmacovigilance matters for Licensed Products and include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of adverse event reports and any other information concerning the safety of any Licensed Product, including recall and withdrawal responsibilities, processes and procedures. Such guidelines and procedures will be in accordance

with, and enable the Parties to fulfill, local and national regulatory reporting obligations under applicable Laws. Each Party hereby agrees to comply with its respective obligations under such Pharmacovigilance Agreement and to cause its Affiliates, Sublicensees and contractors to comply with such obligations.

ARTICLE V
MANUFACTURE, SUPPLY AND COMMERCIALIZATION

5.1 Manufacture and Supply for Initial Development.

(a) Supply. During the Term, until completion of the Technology Transfer as set forth in Section 5.2, and subject to the terms and conditions of this Agreement, OncoC4 will, either by itself or via its Affiliates or a Third Party (i) Manufacture the Licensed Compound and Licensed Products (not including any Other Active) and supply the same to BioNTech for use in Development (including Clinical Trials) of Mono/PD-1 Combinations in accordance with the CDP, and (ii) use Commercially Reasonable Efforts to Manufacture the Licensed Compound and Licensed Products (not including any Other Active) and supply the same to BioNTech for use in Development (including Clinical Trials) of Other Combinations for use under the BioNTech Development Plan. Such Manufacture and supply by or on behalf of OncoC4 to BioNTech shall be governed by a written supply agreement to be negotiated in good faith and mutually agreed and entered into by the Parties as promptly as practicable (but not more than [***] days) following the Effective Date (as may be amended by mutual written agreement of the Parties from time to time, the “**Supply Agreement**”). The Supply Agreement shall be in form and substance customary for a transaction of this type (for clarity, not customary for an arm’s-length Third Party supply arrangement), and include terms and conditions that are in all respects consistent with the terms, conditions, covenants and other arrangements contemplated by this Agreement (including, without limitation, with respect to the sharing of Joint Development Costs and the sharing of liabilities related to the Manufacture of Mono/PD-1 Combinations for purposes of Development in accordance with the CDP), and BioNTech’s responsibility for the cost of Manufacturing for Other Combinations and the Commercialization of Licensed Products. Except as provided under Section 5.1(b) with respect to Joint Development Costs, the cost for Licensed Compound and Licensed Products supplied to BioNTech under the Supply Agreement will be the Fully Burdened Manufacturing Costs for such supply without any mark up. The Parties will mutually agree on a mechanism for the payment or reconciliation of such costs. Following the completion of the Technology Transfer contemplated by Section 5.2, BioNTech, either by itself or via its Affiliates or a Third Party, shall be responsible for all Manufacturing of Licensed Compounds and Licensed Products, including for the supply of the Licensed Compound and Licensed Products to OncoC4 for use by or on behalf of OncoC4 in the Development of Mono/PD-1 Combinations in accordance with the CDP. Except as expressly provided in Section 5.1(b), BioNTech will be responsible for the cost of all such Manufacturing.

(b) Manufacturing Costs. The Parties acknowledge and agree that the Fully Burdened Manufacturing Costs for Licensed Compound and Licensed Products for use in the Development of Mono/PD-1 Combinations in accordance with the CDP shall be included in the Joint Development Costs to be shared by the Parties (whether such costs are incurred by OncoC4 after the Effective Date and prior to the completion of the Technology Transfer, or thereafter by BioNTech). [***]

5.2 Technology Transfer; Further Development and Supply.

(a) Technology Transfer. Subject to Section 5.2(c) with respect to AI-061, upon BioNTech's written request, and to the extent permitted under applicable Third Party manufacturing agreements, OncoC4 shall (i) assign the manufacturing agreements with its Third Party manufacturer(s) relating to the Manufacture of the Licensed Compound and Licensed Products to BioNTech or its designee, or (ii) cause its Third Party manufacturer(s) of the Licensed Compound and Licensed Products to transfer the Manufacturing process of the Licensed Compound and Licensed Products, including any quality assurance, quality control and release assays Controlled by OncoC4 or its Affiliates or the applicable Third Party manufacturer, to BioNTech or its designated Third Party manufacturer to enable BioNTech or such Third Party manufacturer to Manufacture the Licensed Compound and Licensed Products (clauses (i) and (ii) together, the "**Technology Transfer**"). The Parties shall conduct the Technology Transfer in accordance with a mutually agreed technology transfer plan and budget, to be negotiated in good faith and mutually agreed by the Parties within [***] months following BioNTech's written request for the Technology Transfer, which plan shall include (A) detailed activities and timelines for such Technology Transfer, and (B) reasonable on-site support and consultation to be provided by or on behalf of OncoC4. The reasonable FTE Costs and Out-of-Pocket Costs of the Parties incurred in accordance with the Technology Transfer plan and budget in the conduct of such Technology Transfer shall be included in the Joint Development Costs and shared equally (50/50) between the Parties. For clarity, unless otherwise mutually agreed by the Parties in writing, [***] following the completion of such Technology Transfer in accordance with the Technology Transfer plan therefor, OncoC4 and its Affiliates shall have no further obligations or responsibilities with respect to conducting a Technology Transfer of ONC-392 or any other Anti-CTLA-4 Antibody except, if applicable, pursuant to Section 5.2(c).

(b) Further Development and Commercial Supply. Following completion of the Technology Transfer, unless otherwise mutually agreed by the Parties, BioNTech shall be solely responsible for the Manufacture and supply of the Licensed Compound and Licensed Products for all Development and Commercialization in the Field in the Territory, at its own cost, except to the extent that any such Manufacture and supply is for Development activities for Mono/PD-1 Combinations included in the CDP, in which case the Fully Burdened Manufacturing Costs for such supply shall be included in the Joint Development Costs.

(c) Manufacture of AI-025 and AI-061. Unless otherwise mutually agreed by the Parties in writing, the Technology Transfer pursuant to this Section 5.2 shall not include an assignment of agreements for the Manufacturing of AI-025 to BioNTech or its designee but BioNTech shall have the right at any time following Option exercise to receive a technology transfer of the Manufacturing process for AI-025 and AI-061. In that regard, Section 5.2(a) shall apply *mutatis mutandis* to provide for Technology Transfer of such processes for AI-025 and AI-061, except that OncoC4 shall not be required to assign its manufacturing contracts with respect to AI-025 and AI-061 to BioNTech. OncoC4 shall provide all written permissions, consents, waivers, and instructions as BioNTech may reasonably request to facilitate disclosure and Technology Transfer from OncoC4's or its Affiliates manufacturer(s) of AI-025 and AI-061 to BioNTech and/or to allow BioNTech to contract with such manufacturer(s). In addition, if BioNTech exercises the Option in accordance with Section 2.2 and Section 7.2, the Parties will discuss in good faith and mutually agree on terms and conditions under which OncoC4 would, itself or through an Affiliate or Third Party, Manufacture and supply AI-025 to BioNTech or

facilitate a technology transfer of the Manufacturing process for AI-025 to BioNTech or its designee, in either case, to provide for the supply of AI-025 to BioNTech for the further Development and Commercialization of AI-061. For clarity, unless otherwise mutually agreed by the Parties in writing, there shall only be one (1) Technology Transfer under this Section 5.2(c) (to either BioNTech or its designated Third Party manufacturer), and following the completion of such Technology Transfer in accordance with the Technology Transfer plan therefor, OncoC4 and its Affiliates shall have no further obligations or responsibilities with respect to conducting a Technology Transfer of AI-025 or AI-061. Notwithstanding the foregoing, to the extent OncoC4 Manufactures and supplies to BioNTech, either by itself or via its Affiliates or a Third Party, any AI-025 and/or AI-061, OncoC4 shall supply such AI-025 and/or AI-061 at a transfer price equal to or less than OncoC4's FBMC and otherwise pursuant to the other terms and conditions mutually agreed between the Parties in a supply agreement providing for such Manufacture and supply.

5.3 Commercialization.

(a) Commercialization Diligence. BioNTech will be solely responsible for, at its expense, and will have sole discretion with respect to, Commercializing Licensed Products; *provided*, that BioNTech (directly, or through its Affiliates, Sublicensees or contractors) will use Commercially Reasonable Efforts to Commercialize [***]. [***]

(b) Commercialization Plan. [***]

(c) Reporting Obligations. No later than [***] of each Calendar Year during the Term, BioNTech will provide OncoC4 with a high-level summary of BioNTech's Commercialization and Manufacturing activities for each Licensed Product in the Territory performed in the preceding Calendar Year (or updating such summary for activities performed since the last such summary was given hereunder, as applicable), and a high-level summary of the future activities it expects to initiate in the next [***] months after the date of the report. BioNTech shall only be required to commence such summaries as of the date that the JSC disbands. While the JSC continues to meet, BioNTech shall make an annual presentation to the JSC summarizing BioNTech's Commercialization achievements and plans for the following [***] years. Each such report will include a high-level [***] forecast of estimated worldwide Net Sales, which is not required to be broken down by country, territory, region, nor Licensed Product. In addition, BioNTech will provide OncoC4 with written notice of the First Commercial Sale of each Licensed Product in the Territory as soon as reasonably practicable after such event; *provided, however*, that BioNTech will inform OncoC4 of such event prior to public disclosure of such event by BioNTech. BioNTech will provide such other information to OncoC4 as OncoC4 may reasonably request with respect to Commercialization of Licensed Products in the Territory and will keep OncoC4 reasonably informed of the material Commercialization activities of BioNTech with respect to such Licensed Products.

(d) OncoC4 Role In Commercialization. Prior to the commercial launch of a Licensed Product in the United States, upon OncoC4's request to BioNTech, the Parties shall discuss in good faith whether and how OncoC4 might participate in some or all of the Commercialization activities of such Licensed Product in the United States. Additionally, following the first anniversary of the Effective Date, upon OncoC4's reasonable request to BioNTech (not more than once in any Calendar Year unless otherwise mutually agreed), the

Parties shall discuss in good faith the potential Commercialization of Licensed Products in China, including whether and how OncoC4 might participate in some or all of such Commercialization activities and any adjustments to the terms and conditions of this Agreement that may be necessary or desirable to make such Commercialization advantageous to both Parties on commercially reasonable terms and conditions that are consistent with the then-applicable policies, procedures and resources of each Party. Any such participation by OncoC4 in Commercialization activities with respect to Licensed Product(s) would be subject to the negotiation and mutual agreement of the Parties in writing on an amendment to this Agreement or an ancillary agreement setting forth the terms and conditions of such participation. Neither Party is required to agree to such an amendment or ancillary agreement and the inability to, or decision not to, enter in such amendment or ancillary agreement shall not be deemed to indicate that BioNTech has not used Commercially Reasonable Efforts.

ARTICLE VI GOVERNANCE; COLLABORATION STEERING COMMITTEE

6.1 Formation; Purposes and Principles. Within [***] Business Days after the Effective Date, OncoC4 and BioNTech will form a joint steering committee (the “JSC”) to provide oversight and to facilitate information sharing between the Parties with respect to the activities of the Parties under this Agreement. The JSC shall be in existence from the date of its formation until the completion of all then-scheduled activities under the CDP, at which point it shall disband.

6.2 Specific Responsibilities. In addition to its overall responsibility to provide strategic oversight and to facilitate information sharing between the Parties with respect to the activities of the Parties under this Agreement, the JSC will:

(a) review, discuss and approve the CDP and each Joint Development Budget included therein, and any proposed amendments or revisions to the CDP or Joint Development Budget;

(b) oversee and coordinate between the Parties with respect to the Development and Manufacturing activities and interactions with Regulatory Authorities with respect to the Licensed Compound and Licensed Products under the CDP;

(c) coordinate and keep OncoC4 reasonably informed of the BioNTech’s Development, Manufacture and Commercialization activities and interactions with Regulatory Authorities with respect to the Licensed Compound and Licensed Products under the BioNTech Development Plan;

(d) delegate responsibilities to and oversee the activities of any Subcommittees and resolve any disputes raised by the Subcommittees, and

(e) perform such other functions as are assigned to it in this Agreement or as appropriate to further the purposes of this Agreement to the extent agreed to in writing by the Parties.

6.3 Membership. The JSC will be composed of a total of [***] representatives of each Party, which will be appointed by each of OncoC4 and BioNTech, respectively. Each individual appointed by a Party as a representative to the JSC will be an employee of such Party with sufficient seniority within the applicable Party to provide meaningful input and make decisions arising within the scope of the JSC's responsibilities, and have knowledge and expertise in the Development or Commercialization of compounds and products similar to the Licensed Products under this Agreement. The JSC may change its size from time to time by consent of its members; *provided*, that the JSC will consist at all times of an equal number of representatives of each Party, unless otherwise agreed by the Parties in writing. Each Party may replace any of its JSC representatives at any time upon written notice to the other Party, which notice may be given by e-mail, sent to the other Party. The JSC will be co-chaired by one designated representative of each Party, who is a member of the JSC, or alternatively by their designee who has sufficient seniority. Each co-chairperson, or their designee, will alternate being responsible for each meeting for (a) calling and conducting meetings, (b) preparing and circulating an agenda in advance of each meeting; *provided, however*, that the applicable co-chairperson will include any agenda items proposed by either Party on such agenda, (c) preparing minutes of each meeting that reflect the material decisions made and action items identified at such meetings promptly thereafter, and (d) sending draft meeting minutes to each member of the JSC for review and approval within [***] days after each JSC meeting. Each JSC representative will have [***] Business Days from receipt in which to comment on and to approve or provide comments to the minutes (such approval not to be unreasonably withheld, conditioned or delayed). Each JSC representative will be subject to confidentiality obligations no less stringent than those in Section 8.1.

6.4 Meetings. The JSC will hold meetings [***] every [***] during the Term for so long as the JSC exists (i.e., until it disbands in accordance with Section 6.1), unless the Parties mutually agree in writing to a different frequency. No later than [***] Business Days prior to any meeting of the JSC (or such shorter time period as the Parties may agree), the chairperson will prepare and circulate an agenda for such meeting. Either Party may also call a special meeting of the JSC by providing at least [***] Business Days prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, in which event such Party will work with the chairperson of the JSC to provide the members of the JSC no later than [***] Business Day prior to the special meeting with an agenda for the meeting and materials reasonably adequate to enable an informed decision on the matters to be considered. The JSC may meet in person or by audio or video conference as its representatives may mutually agree. Other representatives of the Parties (including relevant Alliance Managers and project managers), their Affiliates, and, only with the advance, written consent of both Parties, Third Parties involved in the Development, Manufacture, or Commercialization of Licensed Products may be invited by the members of the JSC to attend meetings as observers; *provided, however*, that such representatives are subject to confidentiality obligations no less stringent than those set forth in Section 8.1.

6.5 Decision-Making: Escalation to Senior Officers. The Parties will endeavor in good faith and in compliance with this Agreement to reach unanimous agreement with respect to all matters within the JSC's authority. Each Party's representatives on the JSC will collectively have one vote (the "**Party Vote**") on all matters before the JSC, and no action or decision will be taken by the JSC without a unanimous Party Vote (i.e., the affirmative Party Vote of each Party). A decision made in accordance with this Section 6.5 shall be deemed to be a decision made by

the JSC. Should the JSC not be able to reach agreement with respect to a matter at a duly called meeting of the JSC, either Party may refer such matter to the Senior Officers for resolution, and the Senior Officers will attempt to resolve the matter in good faith. If the Senior Officers fail to resolve such matter within [***] days after the date on which the matter is referred to the Senior Officers (unless a longer period is agreed to by the Parties), then:

(a) Subject to Section 2.6(c), BioNTech shall have final decision-making authority on all matters within the JSC's authority; *provided*, that [***].

(i) [***]

(ii) If due to the budgetary impact of a Reserved Financial Decision, BioNTech is unable to exercise its final decision-making authority under Section 6.5(a) to add a new Clinical Trial or new Indication to the CDP and Joint Development Program, then, in any event, BioNTech reserves the right to conduct the Clinical Trial or Develop Licensed Products for the Indication outside the CDP and Joint Development Program, and, in that case, notwithstanding anything express or implied in this Agreement, BioNTech shall have the right, subject to the Reduction Floor, to credit an amount equal to [***] of the Joint Development Costs that would have been OncoC4's responsibility had such Clinical Trial or Development been performed under the CDP against royalties otherwise due hereunder to OncoC4 (in due course as they become due) in respect of the applicable Licensed Product (i.e., royalties payable in respect of the relevant Licensed Product studied in the relevant Clinical Trial or subject of the Development activities conducted by BioNTech outside the CDP) and OncoC4 shall have no right to any Development Milestone Payment in Section 7.4(a) in relation to any Development Milestone Event related to or resulting from such Clinical Trial or Indication, and BioNTech is hereby excused from making such Development Milestone Payments related to such Indications; *provided*, that BioNTech shall only be excused from making a Development Milestone Payment under this Section 6.5(a)(ii) if OncoC4 has not paid Joint Development Costs in respect of the relevant Clinical Trial or the Indication giving rise to the Development Milestone Payment.

(iii) If due to the budgetary impact of a Reserved Financial Decision, BioNTech is unable to exercise its final decision-making authority under Section 6.5(a) to modify a Clinical Trial or the Development of an Indication that is included in the CDP and Joint Development Program as of the applicable time, then, in any event, BioNTech reserves the right to modify the Clinical Trial or modify the Development of Licensed Products for the Indication outside the CDP and Joint Development Program, and, in that case, notwithstanding anything express or implied in this Agreement, BioNTech shall have the right, subject to the Reduction Floor, to credit an amount equal to [***] of the Joint Development Costs that would have been OncoC4's responsibility had such Clinical Trial or Development been performed under the CDP against royalties otherwise due hereunder to OncoC4 (in due course as they become due) in respect of the applicable Licensed Product and the given Indication (i.e., royalties payable in respect of the relevant Licensed Product and Indication studied in the relevant Clinical Trial or subject of the Development activities conducted by BioNTech outside the CDP). In such event, the royalties allocable to the relevant Licensed Product and Indication will be calculated in accordance with a methodology reasonably proposed by BioNTech in good faith, taking in account the respective market share of the Indications. If BioNTech conducts a Clinical Trial or Develops an Indication outside the CDP under this Section 6.5(a)(iii), it shall have no impact on any Development Milestone Payment in Section 7.4(a) in relation to any Development Milestone

Event related to or resulting from such Clinical Trial or Indication, and if any Development Milestone Event occurs with respect to such Clinical Trial or Indication, BioNTech shall be obligated to pay the corresponding Development Milestone Payment in accordance with Section 7.4(a),

(b) Notwithstanding the foregoing or anything contained herein, neither the JSC nor BioNTech through exercise of its final decision-making authority will have the right or authority to (i) amend or waive any of the terms or conditions of this Agreement or otherwise determine any matter outside the authority of the JSC or that expressly requires mutual agreement of the Parties under this Agreement, or (ii) make any determination or take any action solely or specifically related to AI-025 outside the context of AI-061.

6.6 Subcommittees. From time to time during the Term, the JSC may establish and delegate duties to subcommittees (e.g., project teams) (each, a “**Subcommittee**”) on an “as needed” basis to oversee particular projects or activities. Each Subcommittee will consist of mutually agreed number of representatives from each Party, and will meet from time to time upon mutual agreement between representatives from each Party. The decision-making within a Subcommittee will be by consensus, with each Party’s representatives on the applicable Subcommittee collectively having one (1) vote on all matters brought before the Subcommittee. Each Subcommittee and its activities will be subject to the direction, review and approval of, and will report to, the JSC. In no event will the authority of the Subcommittee exceed that specified for the JSC in Section 6.2. Any matter not resolved by a Subcommittee will be referred to the JSC for resolution. Unless otherwise mutually agreed by the Parties, each Subcommittee will disband upon completion of all the obligations designated by the JSC to such Subcommittee.

6.7 Alliance Managers.

(a) Appointment. Each Party will appoint a person to oversee interactions between the Parties for all matters related to the Development and Commercialization of Licensed Products between meetings of the JSC (each, an “**Alliance Manager**”). The Alliance Managers will have the right to attend all meetings of the committees as non-voting participants and may bring to the attention of the JSC any matters or issues either Alliance Manager reasonably believes should be discussed and will have such other responsibilities as the Parties may mutually agree in writing. Each Party may replace its Alliance Manager at any time or may designate different Alliance Managers with respect to Development and Commercialization matters, respectively, by notice in writing to the other Party.

(b) Responsibility. Subject to the limitations set forth in Section 6.5, the Alliance Managers will have the responsibility of creating and maintaining a constructive work environment within the JSC and between the Parties for all matters related to this Agreement. Without limiting the generality of the foregoing, each Alliance Manager will:

(i) provide a single point of communication within the Parties’ respective organizations and between the Parties with respect to this Agreement, including any issues that may arise that it may be possible to resolve without (or prior to) escalation to the JSC;

(ii) coordinate cooperative efforts, internal communications and external communications between the Parties with respect to this Agreement; and

(iii) take such other steps as may be required to ensure that meetings of the JSC occur as set forth in this Agreement, that procedures are followed with respect to such meetings (including working with the co-chairpersons with respect to the giving of proper notice and the preparation and approval of minutes) and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

ARTICLE VII FINANCIAL PROVISIONS

7.1 **Effective Date Payment.** Subject to the terms and conditions of this Agreement, BioNTech will pay OncoC4 a non-refundable, non-creditable, one-time payment in the amount of two hundred million Dollars (\$200,000,000), which payment will be due and payable to OncoC4 within [***] days following the date of BioNTech's receipt of an invoice provided by OncoC4 in accordance with this Agreement upon or after the Effective Date, of which [***] is in consideration for and shall fund the performance by OncoC4 of its activities to research and Develop ONC-392 under the CDP.

7.2 **Option Exercise Fee.** Following BioNTech's delivery of an Option Exercise Notice to OncoC4 in accordance with Section 2.2(a), BioNTech will pay to OncoC4 a non-refundable, non-creditable, one-time payment in the amount of [***] ("**Option Exercise Fee**") no later than [***] days following the date of BioNTech's receipt of an invoice provided by OncoC4 in accordance with this Agreement upon or after the date of OncoC4's receipt of the Option Exercise Notice.

7.3 **Joint Development Costs.**

(a) Except as otherwise provided in Section 3.2, and subject to this Section 7.3, all Joint Development Costs shall be shared equally (50/50) between BioNTech and OncoC4.

(b) Commencing the first Calendar Quarter of the Term and continuing thereafter so long as a Party incurs Joint Development Costs under the CDP, within [***] days after the end of each Calendar Quarter during which either Party incurs any such Joint Development Costs, such Party shall submit to a finance designee of the other Party a report setting forth a good faith estimate of the Joint Development Costs it incurred in such Calendar Quarter, as detailed in the CDP as approved by the JSC. Within [***] days following the end of such Calendar Quarter, each Party shall update such report to reflect the final amount of Joint Development Costs incurred by such Party in such Calendar Quarter; *provided*, that if there are any Joint Development Costs incurred in such Calendar Quarter that a Party is unable to timely include in such financial report, then such amount shall be included and reconciled in the financial report in the following Calendar Quarter. Each such report shall specify in reasonable detail the Joint Development Costs incurred and shall include reasonably detailed supporting information. Within [***] days after receipt of such reports, the finance designees from both Parties shall confer and agree in writing on whether a reconciliation payment is due from one Party to the other Party, and if so, the amount of such reconciliation payment, so that the Parties share Joint Development Costs in accordance with this Section 7.3. The Party required to pay such reconciliation payment shall make such payment to the other Party within [***] days after the date of such Party's receipt of an invoice provided by the other Party upon or after the end of

such [***] day conferral period; *provided, however*, that in the event of any good faith disagreement with respect to the calculation of such reconciliation payment, any undisputed portion of such reconciliation payment shall be paid in accordance with the foregoing timetable and any remaining portion subject to a good faith dispute shall be paid within [***] days after the date on which the Parties, using good faith efforts, resolve the dispute and the Party entitled to payment provides an updated invoice for the correct amount. For the avoidance of doubt, no cost or expense shall be counted more than once in calculating Joint Development Costs, even if such cost or expense falls into more than one of the cost categories that comprise Joint Development Costs.

7.4 Milestone Payments.

(a) Mono/PD1 Combination Development Milestone Payments. During the Term, BioNTech will notify OncoC4 (or, with respect to any Clinical Trial sponsored by OncoC4, OncoC4 will notify BioNTech) in writing of the achievement by or on behalf of BioNTech, its Affiliates or Sublicensees, or OncoC4 of any milestone event set forth in this Section 7.4(a) (each, a “**Development Milestone Event**”): [***] and BioNTech will pay OncoC4 the corresponding non-refundable, non-creditable, milestone payments set forth in the tables below (each, a “**Development Milestone Payment**”) within [***] days following the date of BioNTech’s receipt of an invoice provided by OncoC4 on or after the date of notice of the achievement of the corresponding Development Milestone Event by BioNTech, its Affiliates or any Sublicensees, or OncoC4. For clarity, each of the Development Milestone Events set forth in Section 7.4(a)(i) below [***] may only be earned one time, by the first Mono/PD-1 Combination to achieve the corresponding Development Milestone Event, and the Development Milestone Events set forth in Section 7.4(a)(ii) below [***] may be earned on a [***]

(i) One-Time Development Milestone Payments. Each of the Development Milestone Payments set forth in the table below [***] may be earned once, upon first achievement of the applicable Development Milestone Event by a Mono/PD-1 Combination. For clarity, the maximum amount of all Development Milestone Payments that may be earned under this Section 7.4(a)(i) is [***] as indicated below.

Development Milestone Event	Development Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(ii) Additional Development Milestone Payments. [***].

Development Milestone Event	Development Milestone Payment
[***]	[***]
[***]	[***]

For clarity, [***].

[***]

(b) Sales Milestone Payments. During the Term, BioNTech will pay to OncoC4 each of the non-refundable, non-creditable milestone payments set forth below (each, a “**Sales Milestone Payment**”) within [***] days after the date of BioNTech’s receipt of an invoice provided by OncoC4 in accordance with this Agreement on or after OncoC4’s receipt of the royalty report hereunder that shows the achievement of the corresponding milestone event below (each, a “**Sales Milestone Event**”). Each of the milestone payments set forth in this Section 7.4(b) is payable up to one time only, upon the first achievement of such Sales Milestone Event. For clarity, the maximum amount of all Sales Milestone Payments that may be earned under this Section 7.4(b) is [***].

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

In the calculation of annual aggregate Net Sales for the purposes of the foregoing milestones, for clarity: [***].

Notwithstanding anything express or implied in this Section, no more than one Sales Milestone Payment shall become due with respect to Net Sales levels in any given Calendar Year. Accordingly, if in a given Calendar Year the Net Sales levels would otherwise achieve multiple Sales Milestone Events, then only the Sales Milestone Event associated with the higher or highest such Sales Milestone Event shall be deemed achieved and the corresponding Sales Milestone Payment shall become due once properly invoiced, and the Sales Milestone Events associated with the lower Net Sales level(s) that would otherwise have been first achieved in such Calendar Year shall be deemed not to have been achieved, and will be eligible to be achieved and incur a Sales Milestone Payment in subsequent Calendar Years (subject always to the operation of this paragraph in subsequent Calendar Years).

7.5 Royalties.

(a) Royalty Rate. Subject to the terms and conditions of this Agreement, with respect to [***], BioNTech will pay to OncoC4 non-refundable, non-creditable royalties at the [***] royalty rates specified in the following table with respect [***]:

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

In the calculation of annual aggregate Net Sales for the purposes of the foregoing tiers, for clarity: [***].

(b) Royalty Term. On a [***], unless terminated earlier by either Party pursuant to this Agreement, royalties will be due under Section 7.5(a) [***].

7.6 Royalty Payments and Reports. Within [***] days after the end of each Calendar Quarter, commencing with the Calendar Quarter during which the First Commercial Sale of a Licensed Product is made anywhere in the Territory, BioNTech will provide to OncoC4 a report setting forth: [***]. Concurrent with the provision of the royalty report, BioNTech will request an invoice from OncoC4 for the royalty payment shown in the royalty report, and shall within [***] days after the receipt of the corresponding invoice from OncoC4 (in the amount shown in the royalty report) pay OncoC4 the royalties due to OncoC4 with respect to Net Sales by BioNTech, its Affiliates and their respective Sublicensees for such Calendar Quarter.

7.7 Royalty Payment Reductions. The royalties payable under Section 7.5 will be subject to the following:

(a) Third Party IP. If BioNTech or its Affiliate or a Sublicensee is a party to, as of the Effective Date or thereafter, enters into a license or settlement agreement with a Third Party for the right under any Patent owned or Controlled by such Third Party [***] – and pursuant to such agreement makes payments (which may include license fees, milestones, and net sales royalties) to such Third Party for such right to Commercialize such Licensed Product under such Patent, then, subject to Section 7.7(f), BioNTech may deduct [***] of such payments actually paid to such Third Party for such right under such Patent in a Calendar Quarter against the royalties due and payable to OncoC4 on the Net Sales for such Licensed Product due in respect of such Calendar Quarter under this Agreement.

(b) Lack of Patent Protection. Subject to Section 7.7(f), if at any time during the Royalty Term, for any Licensed Product in a given country in the Territory, the last-to-expire Valid Claim in any Licensed Patent or [***] Covering such Licensed Product in such country expires or otherwise ceases to be a Valid Claim, then, from the first Calendar Quarter in which this Section 7.7(b) applies, and thereafter for so long as this Section 7.7(b) applies, the applicable royalties in effect with respect to such Licensed Product in such country as specified in Section 7.5(a) will be [***] by [***]. For this purpose, “last-to-expire” means the last to expire or last to continue to qualify as a Valid Claim.

[***]

(c) [***]

(d) Compulsory License. Subject to Section 7.7(f), if a Compulsory License is granted to a Third Party with respect to a Licensed Product in a given country with a royalty rate lower than the applicable royalty rate in such country hereunder, then the royalties payable to OncoC4 with respect to such Licensed Product in such country in an applicable Calendar Quarter shall be reduced to [***]. Notwithstanding Section 7.7(f), if the compulsory licensee receives its grant of rights from BioNTech at royalty rate(s) lower than those of this Agreement, they shall be excluded from the definition of “Sublicensee,” and BioNTech shall pass through the compulsory licensee’s royalties to OncoC4 but shall not owe the higher royalty rate set forth herein on the compulsory licensee’s sales. Moreover, it is understood that the compulsory licensee, even if receiving its governmentally-mandated rights from BioNTech, shall

notwithstanding anything express or implied contained herein, remain a Third Party who will be deemed not to be a Sublicensee hereunder and whose sales of Licensed Product may give rise to (and be counted towards) the existence of Biosimilar Competition in the applicable country.

(e) Biosimilar Competition. Subject to Section 7.7(f), [***], during the Royalty Term for a Licensed Product in a country, if there is Biosimilar Competition with respect to such Licensed Product in such country, then, from the first Calendar Quarter in which such Biosimilar Competition occurs, and thereafter for each Calendar Quarter for which such Biosimilar Competition exists, the applicable royalties in effect with respect to such Licensed Product in such country as specified in Section 7.5(a) will be [***] by [***].

(f) Cumulative Deductions. Notwithstanding the foregoing, in no event will the deductions set forth in Sections [***], individually or in the aggregate, reduce the royalties otherwise payable to OncoC4 under Section 7.5 with respect to a given Licensed Product in a country in a Calendar Quarter by more than [***] (such percentage, the “**Reduction Floor**”); *provided, however*, (i) with respect to a Licensed Product in a country, if Biosimilar Material Competition occurs with respect to such Licensed Product in such country, then, from the first Calendar Quarter in which such Biosimilar Material Competition occurs, and thereafter for each Calendar Quarter for which such Biosimilar Material Competition exists, the Reduction Floor for such Licensed Product in such country shall be decreased from [***] [***] to [***] of the royalties otherwise payable to OncoC4 under Section 7.5 for such Licensed Product in such country in such Calendar Quarter; and (ii) with respect to a Licensed Product in a country, if there is no Valid Claim in any Licensed Patent or [***] Covering such Licensed Product in such country, or if there is Biosimilar Competition in such country, then, from the first Calendar Quarter in which there is no Valid Claim or there is Biosimilar Competition in such country, and thereafter for each Calendar Quarter for which there is no Valid Claim or there is Biosimilar Competition in such country, the applicable Reduction Floor with respect to royalty reductions pursuant to: (X) Third Party payments pursuant to Section 7.7(a); (Y) Development costs as a result of a Reserved Financial Decision pursuant to Section 6.5(a); and (Z) Development costs pursuant to Section 3.2(f), in each case (for clarity, together with all other royalty reductions for such Licensed Product in such country), shall be decreased from [***] to [***] of the royalties otherwise payable to OncoC4 under Section 7.5 for such Licensed Product in such country in such Calendar Quarter, and *provided, further*, that, if BioNTech is unable to deduct or credit any portion of any royalty deductions or credits set forth in this Agreement not already offset against royalties hereunder in any Calendar Quarter as a result of the applicable Reduction Floor then it shall be able to carry the remaining not-yet-offset deduction(s) forward to future Calendar Quarters and offset them against royalties hereunder. For avoidance of doubt, Development costs deducted pursuant to subclauses (Y) and (Z) may be taken globally and without reference to a specific country.

7.8 Financial Audits.

(a) Record Keeping. BioNTech and its Affiliates will, and will cause their respective Sublicensees to, keep complete, true and accurate books and records in accordance with its Accounting Standards of the items underlying (i) Net Sales and (ii) royalty payments under this Agreement. BioNTech and its Affiliates will, and will cause their respective Sublicensees to keep, such books and records for at least [***] years following the Calendar Quarter to which they pertain. OncoC4 will have the right annually, at its own expense, to have

an internationally-recognized independent, certified public accountant, selected by OncoC4 and reasonably acceptable to BioNTech (the “**Auditor**”), review any such records of BioNTech and its Affiliates in the location(s) where such records are customarily maintained by BioNTech upon reasonable prior notice, during regular business hours and under obligations of confidentiality, except to the extent necessary to enforce OncoC4’s rights under this Agreement or if disclosure is required by applicable Law, for the sole purpose of verifying the basis and accuracy of payments made under this Agreement and the content of the reports described in Section 7.6, within the prior [***] Calendar Year period after receipt of such report. The Auditor will have the right to disclose to OncoC4 its conclusions regarding any payment owed under this Agreement. The records for any Calendar Year may be audited no more than once with respect to records covering any specific period of time. BioNTech shall obtain for itself or its Affiliate a commensurate right for it to audit Sublicensees, and either exercise that right itself upon the written request of OncoC4, or allow OncoC4 to hire the Auditor to conduct the audit of the Sublicensee records.

(b) Audit Report. The report prepared by the Auditor, a copy of which will be sent or otherwise provided to each Party by such Auditor at the same time before such report is considered final, will contain the conclusions of such Auditor regarding the audit and will specify that the amounts paid pursuant thereto were correct or, if incorrect, the amount of any underpayment or overpayment, and the specific details regarding any discrepancies. No other information will be provided to OncoC4 without the prior consent of BioNTech unless disclosure is required by Laws, regulation or judicial order, and if so determined by OncoC4, it will, if permitted, give BioNTech prior notice thereof to the extent possible for BioNTech to seek a protective order against or limiting such disclosure. If such report shows any underpayment, then BioNTech will remit to OncoC4, within [***] Business Days after receipt of such report, (i) the amount of such underpayment and (ii) if such underpayment exceeds [***] of the total amount owed for the period then being audited, the actual costs incurred by OncoC4 in conducting such review will be reimbursed. For the avoidance of doubt, payment of the underpayment will be considered a late payment, subject to Section 7.11. If such report shows any overpayment, then BioNTech will have the right to credit the overpaid amount against future payments owed to OncoC4 or, if further payments will not be due hereunder within [***] days, require that OncoC4 reimburse the amount of such overpayment. The Parties mutually agree that the information subject to review under this Section 7.8 is Confidential Information of BioNTech and that OncoC4 will retain and cause the Auditor to retain all such information in confidence in accordance with confidentiality and non-use obligations no less stringent than those contained in Section 8.1.

(c) Each Party shall also have an audit right equivalent to the audit right set forth in Section 7.8(a)-(b) (applied *mutatis mutandis*) to audit the other Party’s and its Affiliates records with respect to Joint Development Costs, to confirm the accuracy of the Joint Development Costs asserted by the audited Party.

7.9 Tax.

(a) Income Taxes. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly under this Agreement.

(b) Tax Withholding. Any tax paid or required to be withheld by BioNTech under applicable Laws in effect at the time of payment for the benefit of OncoC4 on account of any royalties or other payments payable to OncoC4 under this Agreement shall be deducted from the amount of royalties or other payments otherwise due. The Parties shall reasonably cooperate with one another to reduce or minimize any such deduction or withholding required by applicable Laws, including by providing any documents, information, forms or other certifications necessary to reduce the amount of such withholding. The Parties shall also reasonably cooperate with one another, in good faith, with respect to all documentation and actions required by the German tax authorities to secure a reduction in the rate of applicable withholding taxes, including (i) obtaining a certificate of exemption from withholding taxes from the German tax authorities, or (ii) to the extent permitted under applicable Law, obtaining a repayment or refund of an amount previously withheld and remitted to the German tax authorities. For clarity, the Parties hereby provide their consent to disclose this Agreement to the German tax authorities for purposes of obtaining such a certificate or a tax refund. If, in accordance with the foregoing, BioNTech withholds any amount, then it will pay to OncoC4 the balance when due, timely remit to the proper taxing authority the withheld amount, and send OncoC4 proof of such remittance within [***] days following OncoC4's request for such proof of remittance. If and to the extent BioNTech receives from a tax authority a repayment or refund of an amount previously withheld and remitted pursuant to this Section 7.9(b), BioNTech shall notify OncoC4 and pay such repaid or refunded amount to OncoC4 without undue delay.

(c) Notwithstanding the foregoing, BioNTech shall assume the responsibility for, and increase the amount payable hereunder such that OncoC4 receives the amount it would have received but for, any Incremental Withholding (as defined below) in the event that such Incremental Withholding arises as a result of any Withholding Action by or on behalf of BioNTech. For purposes hereof, a "**Withholding Action**" by or on behalf of BioNTech means any action taken, or caused to be taken, by BioNTech or its Affiliate (including any assignment of this Agreement, in whole or in part) that results or would result in any additional withholding or reduction from payments made hereunder (any such amount withheld or deducted, an "**Incremental Withholding**") which would not have resulted absent BioNTech or such Affiliate taking, or causing to be taken, such action.

(d) VAT and Indirect Taxes. All amounts payable under or in connection with this Agreement are exclusive of VAT and Indirect Taxes. Any VAT and Indirect Taxes payable on the consideration shall be paid by BioNTech at the same time as the payment or provision of the consideration to which it relates. If any VAT and Indirect Taxes are paid by OncoC4 to the relevant fiscal authority before such payment is made by BioNTech, BioNTech shall reimburse OncoC4 such VAT and Indirect Taxes within [***] days following receipt of the relevant invoice from OncoC4.

(e) Provision of Documents. OncoC4 is required to provide all invoice and customs related documents to [***] and [***] on a [***] basis.

7.10 Currency of Payments. All amounts payable and calculations under this Agreement will be in Dollars. As applicable, Net Sales and any royalty reductions will be translated into Dollars using the average exchange rates published by the European Central Bank and in accordance with the Accounting Standards (or any other qualified source that is acceptable to both Parties) for the [***] in which such Net Sales occurred, where Accounting

Standards refers to the Accounting Standards of the Party who owes a payment to the other Party. All payments under this Agreement will be paid in Dollars by wire transfer to an account designated by the receiving Party (which account the receiving Party may update from time to time in writing).

7.11 Payment in Full. Except to the extent permitted under Section 7.9 or 15.11 or otherwise required by applicable Law in effect at the time of payment, each Party will make all payments due hereunder (including any amounts payable pursuant to ARTICLE XI) in full without set-off or counterclaim of any kind.

7.12 Late Payments. Without limiting any other rights or remedies available to either Party hereunder, any late payment by one Party to the other will bear interest, to the extent permitted by Laws, at an annual rate of [***], computed from the date such payment was due until the date the paying Party makes the payment.

7.13 Costs of Upstream Agreements. In accordance with and without limiting Section 2.7, except as set forth in Section 10.2(k), OncoC4 shall be wholly responsible for any and all payments due pursuant to the Upstream Agreements, including all milestones and royalties due under the Upstream Agreements in respect of Development, Manufacturing (without limiting ARTICLE V), Commercialization, achievements, and sales that occur under or pursuant to a right granted in this Agreement.

7.4 Invoices. Notwithstanding anything contained herein, in the event of any good faith disagreement with respect to the amount or calculation of an amount set forth in an invoice delivered to BioNTech by OncoC4 hereunder, any undisputed portion of the applicable amount shall be paid in accordance with the terms hereof and any remaining portion subject to a good faith dispute shall be paid within [***] days after the date on which the Parties, using good faith efforts, resolve the dispute and, if applicable, OncoC4 provides an updated invoice for the correct remaining amount.

ARTICLE VIII **INTELLECTUAL PROPERTY**

8.1 Ownership.

(a) Licensed Know-How and Licensed Patents. Subject only to the rights expressly granted to BioNTech under this Agreement, as between the Parties, OncoC4 will retain all rights, title and interests in and to the Licensed Know-How and Licensed Patents. In addition, each Party shall own any Patent or Know-How created or obtained by or on behalf of such Party independently and outside the scope of the collaboration between the Parties under this Agreement (as such scope may be limited pursuant to Section 2.6).

(b) [***].

(i) Any inventions and Know-How (whether or not patentable) that are conceived, discovered, developed, reduced to practice, or otherwise made, either solely or jointly by or on behalf of (including that arising from contractors' activities): (A) OncoC4 and its Affiliates on the one hand, or (B) BioNTech, its Affiliates and Sublicensees on the other hand, in

the course of performing any activities under the CDP, including and any other intellectual property rights therein and thereto [***], and any Patents that claim such [***].

(ii) Subject to the license grants in Section 2.1 [***].

(c) [***].

(i) Any inventions and Know-How (whether or not patentable) that are conceived, discovered, developed, reduced to practice, or otherwise made, either solely or jointly by or on behalf of (A) OncoC4 and its Affiliates on the one hand, or (B) BioNTech, its Affiliates and Sublicensees on the other hand, [***].

(ii) Any inventions and Know-How (whether or not patentable) that are conceived, discovered, developed, reduced to practice, or otherwise made, either solely or jointly by or on behalf of (A) OncoC4 and its Affiliates on the one hand, or (B) BioNTech, its Affiliates and Sublicensees on the other hand, in each case, in the course of performing their respective activities under this Agreement, [***].

(d) [***]. Any inventions and Know-How (whether or not patentable) that are conceived, discovered, developed, reduced to practice, or otherwise made, either solely or jointly by or on behalf of (A) OncoC4 and its Affiliates on the one hand, or (B) BioNTech, its Affiliates and Sublicensees on the other hand, in each case, in the course of performing their respective activities under this Agreement, [***].

(e) Assignment Obligation. Each Party will cause its Affiliates, sublicensees, and its and their directors, officers, employees, consultants, contractors, and agents to assign to such Party all of such individuals' right, title, and interest in and to the [***] that are conceived, discovered, developed, reduced to practice, or otherwise made by such individual, together with all Patents claiming such [***]. OncoC4 shall and hereby does assign to BioNTech all right, title and interest in and to all [***]. BioNTech shall and hereby does assign to OncoC4 all right, title and interest in and to all [***].

8.2 Patent Prosecution.

(a) Licensed Patents and [***].

(b) [***]

(c) Cooperation in Prosecution. Each Party will, and will cause its Affiliates to, reasonably cooperate, with the other Party with respect to [***], including transferring copies of relevant files and records relating to Prosecution of such Patents, providing any necessary powers of attorney, complying with any applicable duty of candor or disclosure with a patent office and executing any other required documents or instruments for such Prosecution.

(d) Patent Term Extension. If elections with respect to obtaining patent term extension or supplemental protection certificates or their equivalents in any country (collectively, "**Patent Extension**") with respect to [***] become available, the Parties will discuss in good

faith and seek to mutually agree on which [***] to extend; *provided*, that if the Parties cannot agree in good faith[***].

(e) Data Exclusivity, Purple Book and Patent Register Listings. With respect to data exclusivity periods (such as those periods listed in the Purple Book (including any available pediatric extensions) or periods under national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83, and all equivalents in any country), (i) with respect to the Licensed Products, the Parties will coordinate, and each Party shall, in consultation with the other Party and after consideration in good faith of such other Party's comments, seek and maintain all such data exclusivity periods that may be available for any of the Licensed Products, and determine which Licensed Patents, [***], if any, will be listed with the applicable Regulatory Authorities for any Licensed Product in its field, including all so-called "Patent Register" listings required by certain Governmental Authorities, and all similar listings in any other relevant countries.

(f) Upstream Agreements. Notwithstanding anything contained herein, this Section 8.2 shall not apply to any Licensed Patents that OncoC4 Controls pursuant to an Upstream Agreement to the extent that there are any conflicts between the provisions hereof and the applicable Upstream Agreement, in which case, the terms and conditions of the applicable Upstream Agreement shall control with respect to the Prosecution of such Licensed Patents. To the extent that OncoC4 is required to make any payments to a Third Party licensor under an Upstream Agreement with respect to any Prosecution of any Licensed Patents thereunder, BioNTech shall reimburse OncoC4 for such payments within [***] days after receipt of an undisputed invoice from OncoC4 in accordance with this Agreement regarding the same; *provided*, that if these costs are due because of OncoC4's exercise of its step-in rights, then OncoC4 shall be solely responsible for those costs.

8.3 Third Party Infringement.

(a) Notice. Each Party will promptly notify the other in writing of any (i) suspected, threatened or actual infringement by a Third Party of any Licensed Patent [***];(ii) suspected, threatened or actual unauthorized disclosure, use or misappropriation of any Licensed Know-How or [***] by a Third Party, or (iii) any actual or threatened allegations of alleged patent invalidity, unenforceability or non-infringement of a Licensed Patent [***] in connection with a Biosimilar Application, or any other similar patent certification by a Third Party, and any foreign equivalent thereof, in each case ((i) – (iii)), of which it becomes aware, and will provide the other Party with full particulars and all evidence in such Party's possession or control supporting such infringement, unauthorized use or misappropriation, or allegations or certifications (each, an "IP Notice").

(b) [***]

(c) [***]

(d) [***]

(e) [***]

(f) Biosimilar Applications.

(i) If either Party receives a copy of an application submitted to the FDA under subsection (k) of Section 351 of the PHSA (a “**Biosimilar Application**”) naming a Licensed Product as a reference product or otherwise becomes aware that such a Biosimilar Application has been filed (including by the receipt of information disclosed pursuant to Section 351(l)(2) of the PHSA, or in an instance described in Section 351(l)(9)(C) of the PHSA), either Party will, within ten (10) Business Days thereafter, notify the other Party so that the other Party may seek permission to view the application and related confidential information from the filer of the Biosimilar Application under Section 351(l)(1)(B)(iii) of the PHSA. If either Party receives any equivalent or similar certification, information or notice in any other jurisdiction in the Territory naming a Licensed Product, either Party will, within ten (10) Business Days thereafter, notify and provide the other Party with copies of such communication.

(ii) Solely with respect to a Biosimilar Application referring to a Licensed Product in the Field, regardless of the Party that is the “reference product sponsor” for purposes of such Biosimilar Application, (A) [***] to designate pursuant to Section 351(l)(1)(B)(ii) of the PHSA the outside counsel and in-house counsel who will receive confidential access to the Biosimilar Application, (B) [***] to (1) list any Licensed Patents, [***] and any other Patents, as required pursuant to Section 351(l)(3)(A), Section 351(l)(5)(b)(i)(II), or Section 351(l)(7) of the PHSA, (2) respond to any communications with respect to such lists from the filer of the Biosimilar Application, and (3) negotiate with the filer of the Biosimilar Application as to whether to utilize a different mechanism for information exchange than that specified in Section 351(l) of the PHSA; and (C) [***], to identify Licensed Patents, [***] and any Patents, and to respond to communications under any equivalent or similar listing in any other jurisdiction in the Territory in accordance with Section 8.2(f). [***]

(g) Cooperation. In any Action under Section 8.3, each Party will, and will cause its Affiliates to, reasonably cooperate with the other Party, in good faith, relative to the efforts to protect the Licensed Patents [***] and will join such suit as a party, if requested by the other Party. Furthermore, the Party initiating any Action pursuant to Section 8.3(b) or Section 8.3(c) will consider in good faith all reasonable and timely comments from the other Party on any proposed arguments asserted or to be asserted in litigation related to the enforcement or defense of any such Patents. [***]

(h) Upstream Agreements. Notwithstanding anything contained herein, [***] are subject to the applicable terms and conditions of such Upstream Agreement with respect to any such Licensed Patents, as applicable.

(i) Expenses. Subject to Section 8.3(j) and unless otherwise expressly provided for under this Section 8.3, [***].

(j) Allocation of Recoveries. Any settlements, damages or monetary awards recovered by either Party pursuant to any Action under this Section 8.3 with respect to the Licensed Patents [***] will, [***].

8.4 Claimed Infringement. Each Party will promptly notify the other Party if a Third Party brings any Action alleging patent infringement by BioNTech or OncoC4 or any of their respective

Affiliates or Sublicensees with respect to the Development, Manufacture or Commercialization of any Licensed Product (any such Action, an “**Infringement Claim**”) in the Territory. [***]

8.5 Common Legal Interest/Joint Defense. All information exchanged between the Parties regarding the prosecution and maintenance, and enforcement and defense, of Licensed Patents [***] under this ARTICLE VIII will be deemed Confidential Information of the disclosing Party. In addition, the Parties acknowledge and agree that, with regard to such prosecution and maintenance, and enforcement and defense, the interests of the Parties as collaborators and licensor and licensee are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. Notwithstanding anything contained herein, to the extent a Party has a good faith belief that any information required to be disclosed by such Party to the other Party under this ARTICLE VIII is protected by attorney-client privilege or any other applicable legal privilege or immunity, such Party will not be required to disclose such information except under circumstances designed to preserve such privilege, and the Parties will in good faith cooperate to agree upon a procedure (including entering into a specific common legal interest/joint defense agreement, disclosing such information on a “for counsel eyes only” basis or similar procedure) under which such information may be disclosed without waiving or breaching such privilege or immunity.

8.6 Patent Marking. If required by law, BioNTech will mark, and will cause all of its Affiliates and Sublicensees to mark, Licensed Products with all Licensed Patents in accordance with applicable Law, which marking obligation will continue for as long as required under applicable Law.

8.7 Extension of Rights to BioNTech Affiliate, Sublicensee. BioNTech shall be entitled to extend its rights in this ARTICLE VIII to, or exercise its rights and perform its obligations in this Article by, an Affiliate or a Sublicensee, notwithstanding anything express or implied in this Article.

8.8 Additional Third Party Intellectual Property. Other than the Patents and Know-How that are Controlled by OncoC4 pursuant to the Upstream Agreements, during the Term, if OncoC4 becomes aware of Patents or Know-How of any Third Party that it believes may be useful to license for purposes of Development and/or Commercialization of Licensed Compound(s) and/or Licensed Product(s), OncoC4 shall notify the JSC or a patent subcommittee thereof or a committee consisting of patent counsel for each Party, of such Patents and Know-How (as applicable) for BioNTech’s consideration. [***]

8.9 Bankruptcy; Intellectual Property. All rights and licenses granted under or pursuant to this Agreement by a bankrupt Party to the other Party are, and shall be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code and any similar law or regulation in any other country, licenses of rights to “intellectual property” as defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that all intellectual property rights licensed hereunder, are part of the “intellectual property” as defined under Section 101(35A) of the Bankruptcy Code subject to the protections afforded

the non-terminating Party under Section 365(n) of the Bankruptcy Code, and any similar law or regulation in any other country. [***]

ARTICLE IX CONFIDENTIALITY AND PUBLICITY

9.1 Confidential Information.

(a) Confidentiality Obligation. During the Term and for a period of [***] years after any termination or expiration of this Agreement, each Party agrees to, and will cause its Representatives to: (i) keep in confidence and not disclose the other Party's Confidential Information to any Third Party without the prior written consent of the disclosing Party, except as expressly permitted pursuant to this Agreement; and (ii) not use for any purpose, except to exercise its rights or perform its obligations under this Agreement, any Confidential Information of the other Party, without the prior written consent of the disclosing Party. The existence and terms of this Agreement are the Confidential Information of each Party, with each Party treated as the receiving Party.

(b) Permitted Disclosures. Each Party agrees that it and its Affiliates will provide or permit access to the other Party's Confidential Information only to the receiving Party's employees, consultants, advisors and Sublicensees, and to the employees, consultants and advisors of the receiving Party's Affiliates (collectively, "**Representatives**"), in each case, of all the foregoing in this Section 9.1(b), on a need to know basis (meaning they need to know the information for purposes of performing the Party's obligations under this Agreement or exercising its rights under this Agreement), who are subject to obligations of confidentiality and non-use with respect to such Confidential Information no less stringent than the obligations of confidentiality and non-use of the receiving Party pursuant to this Section 9.1 (but of duration customary in confidentiality agreements entered into for a similar purpose). Each Party will remain responsible for any failure by its Affiliates or Sublicensees, and its and its Affiliates' respective employees, consultants and advisors, to treat such Confidential Information as required under this Section 9.1 as if such Affiliates, employees, consultants, advisors and Sublicensees were parties directly bound to the requirements of this Section 9.1.

(c) Confidentiality Limitation. Notwithstanding anything herein, each Party may use and disclose the other Party's Confidential Information and the terms of this Agreement as follows: (i) by BioNTech or its Affiliates under appropriate written confidentiality and non-use obligations no less stringent than those in this Agreement (but of duration customary in confidentiality agreements entered into for a similar purpose), to bona fide potential or actual collaborators, licensors, Sublicensees, licensees, or strategic partners and, on a need to know basis, to employees, directors, agents, consultants, and advisers of any such Third Parties, (ii) by OncoC4 or its Affiliates under appropriate written confidentiality and non-use obligations no less stringent than those in this Agreement (but of duration customary in confidentiality agreements entered into for a similar purpose), to permitted contractors, sublicensees and Service Providers and, on a need to know basis, to employees, directors, agents, consultants, and advisers of any such Third Parties, (iii) by either Party to its financial advisors, attorneys and accountants, to bona fide actual or potential acquisition partners, financing sources, investors and underwriters on a need to know basis, in each case, under appropriate confidentiality and non-use obligations (which may include professional ethical obligations) no less stringent than those in this

Agreement (but of duration customary in confidentiality agreements entered into for a similar purpose); *provided, however*, that each Party will remain responsible for any failure by any of the foregoing individuals or entities to treat such Confidential Information as required under Section 9.1 as if such individuals or entities were parties directly bound to the requirements of this Section 9.1, or (iv) as required by any court or other governmental body or as otherwise required by applicable Laws (including any such disclosures as are required by a Regulatory Authority in connection with seeking Regulatory Approval, Pricing and Reimbursement Approval, import authorization for any Licensed Product in the Territory, or the rules or regulations of the United States Securities and Exchange Commission or similar Regulatory Authority in a country other than the United States or of any stock exchange or listing entity); *provided*, that except for disclosures of Confidential Information to any Regulatory Authority, notice is promptly given to the other Party and the disclosing Party cooperates with reasonable requests from the other Party to seek a protective order or other appropriate remedy to protect the Confidential Information. Notwithstanding anything to the contrary contained in this ARTICLE IX, Confidential Information that is permitted or required to be disclosed will remain otherwise subject to the confidentiality and non-use provisions of Section 9.1(b) and this Section 9.1(c) if it does not as a result of any of the foregoing disclosures become public. If either Party concludes that a copy of this Agreement must be filed with the United States Securities and Exchange Commission or similar Regulatory Authority in a country other than the United States, then such Party will, a reasonable time (and in no event less than [***] Business Days) prior to any such filing, provide the other Party with a copy of such agreement showing any provisions hereof as to which the Party proposes to request confidential treatment, will provide the other Party with an opportunity to comment on any such proposed redactions and to suggest additional redactions, and will take such other Party's reasonable comments into consideration before filing such redacted version of the Agreement and use Commercially Reasonable Efforts to have terms identified by such other Party afforded confidential treatment by the applicable Regulatory Authority provided that such confidential treatment is reasonably available for the terms requested.

(d) Secrecy of Licensed Know-How. Without limiting the generality of Section 9.1(a), during the Term each Party will protect, and will cause its Affiliates and its Sublicensees and its and their respective officers, directors, employees, and agents to protect, the secrecy and confidentiality of the Licensed Know-How and unpublished Licensed Patents [***] using at least the same degree of care as it uses to prevent the disclosure of its own other confidential information of like importance and in any event a reasonable duty of care.

9.1 Publicity. The Parties acknowledge that in some cases it may be desirable to publicly disclose results and significant Developments regarding a Licensed Product in the Field in the Territory, and such disclosures shall be permitted in the circumstances described in this Section 9.2. Such disclosures may include achievement of milestones, significant events in the Development process with respect to Licensed Products, or Commercialization activities with respect to Licensed Products.

(a) Except for disclosures permitted in accordance with Section 9.1(b), whenever either Party elects to make any public disclosure regarding this Agreement, including any milestones, significant events in the Development or Commercialization of the Licensed Products in the Territory, it will first notify the other Party of such planned press release or public announcement and provide a draft for review no less than [***] Business Days in advance

of issuing such press release or making such public announcement (or, with respect to press releases and public announcements that are required by applicable Laws, with as much advance notice as possible under the circumstances if it is not possible to provide notice no less than [***] Business Days in advance). Each Party will have the right to review any such planned press release or public announcement proposed by the other Party with respect to Licensed Products in the Territory, or that includes Confidential Information of the other Party. The reviewing Party will attempt to provide to the other Party its feedback as to whether it approves or withholds its consent as soon as reasonably possible, typically no later than [***] Business Days after its receipt thereof. A Party desiring to make such public disclosure may issue such press release or public announcement without such prior review by the other Party if (1) the contents of such press release or public announcement have all previously been made public other than through a breach of this Agreement by such Party, and (2) such press release or public announcement is consistent with the previously issued press release or other publicly available information. In addition, the non-disclosing Party will have the right to review, but not approve, any press release or public announcement that the proposing Party determines is required by applicable Laws based on the advice of counsel, which public disclosures are subject to Section 9.2. Notwithstanding the foregoing, the Parties have agreed to issue a joint press release in substantially the form attached hereto as Schedule 9.2(a) on a date to be mutually agreed by the Parties.

(b) The principles to be observed in such disclosures will include accuracy, compliance with applicable Laws and regulatory guidance documents, reasonable sensitivity to potential negative reactions of Regulatory Authorities and the need to keep investors informed regarding the business of the Party making such public disclosure. Nothing in this Section 9.2 will restrict a Party from making a disclosure required by Laws as reasonably determined by such Party's counsel, including disclosures in clinical trial registries and those required by any Laws relating to the public sale of securities (as provided in Section 9.1(c)); *provided, however*, that such disclosure will include no more Confidential Information than the amount required by such applicable Laws, and the Parties will use reasonable efforts to seek confidential treatment of Confidential Information to be included in such disclosures.

(c) Except with the prior written approval of BioNTech or otherwise in accordance this ARTICLE IX, OncoC4 shall have no right to publish or present the results of the Joint Development Program. In the event that BioNTech proposes to publish or present the results of the Joint Development Program, including any oral presentation or abstract, such publication or presentation will be subject to the prior review by OncoC4 for patentability and the inclusion of Confidential Information. BioNTech will provide to OncoC4 the opportunity to review any proposed abstracts, manuscripts or summaries of presentations that cover the results of the Joint Development Program. OncoC4 will respond in writing promptly and in no event later than [***] Business Days after receipt of the proposed material with either approval of the proposed material or a specific statement of concern, based upon either the need to seek patent protection or removal of OncoC4's Confidential Information. OncoC4 may also express any concern it may have regarding competitive disadvantage arising from the proposal. In the event of any such concern provided in accordance with this Section 9.2(c), BioNTech agrees not to submit such publication or to make such presentation that contains such information for a period of [***] days in order to provide time to seek patent protection or otherwise resolve such concern. In addition, BioNTech will remove from such proposed publication any Confidential

Information of OncoC4 as requested by OncoC4 that is not also the Confidential Information of BioNTech.

(d) BioNTech will not submit or publish any article or other publication to or with any scientific journal or other publisher that requires, as a condition of publication, that BioNTech agrees to make available to the publisher or Third Parties any written materials that are the subject of the publication without prior written consent of OncoC4 before making such materials available to the publisher, such consent not to be unreasonably withheld, delayed or conditioned. BioNTech will reasonably consider in good faith OncoC4's timely communicated requests and concerns with respect to any publication proposed by BioNTech. All publications made by BioNTech relating to any Licensed Product or Licensed Compound will be prepared, presented, and published in accordance with generally accepted pharmaceutical industry customs and guidelines, including with respect to attribution.

(e) Notwithstanding any other provision of this Agreement, OncoC4 and its Affiliates shall have the right to publish the results or summaries of results of Clinical Trials (including meta-analysis or observational studies) conducted by or on behalf of OncoC4 or its Affiliates with respect to a Licensed Compound or Licensed Products as contemplated by Section 3.3(c) to the extent required under applicable Laws or applicable industry codes; *provided*, that OncoC4 will provide BioNTech a reasonable opportunity to review any proposed publication under this Section 9.2(e) prior to its publication for patentability and the inclusion of Confidential Information not required to be published or disclosed under applicable Laws or industry codes. BioNTech will respond in writing promptly and in no event later than [***] Business Days after receipt of material proposed to be published under this Section 9.2(e) with either approval of the proposed material or a specific statement of concern, based upon either the need to seek patent protection or removal of BioNTech Confidential Information that is not required to be published or disclosed under applicable Laws or industry codes. In the event of any such concern provided in accordance with this Section 9.2(e), OncoC4 agrees not to submit the applicable information for publication for a period of [***] days in order to provide time for BioNTech to seek patent protection or otherwise resolve such concern. In addition, OncoC4 will remove from such proposed publication any Confidential Information of BioNTech as requested by BioNTech or required to be published under applicable Law or industry codes. Subject to prior review by BioNTech and the express terms of this Section 9.2(e), BioNTech may not prevent OncoC4 from publishing the results or summaries of results of Clinical Trials conducted by or on behalf of OncoC4 or its Affiliates to the extent required by applicable Laws or applicable industry codes, and publications made by OncoC4 in accordance with this Section 9.2(e) shall not be a breach of OncoC4's obligations of confidentiality or non-use under this Agreement.

9.3 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that could result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages will not be a sufficient remedy for any breach of this ARTICLE IX. In addition to all other remedies, a

Party will be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this ARTICLE IX.

ARTICLE X
REPRESENTATIONS AND WARRANTIES; CERTAIN COVENANTS

10.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party that, as of the Execution Date and the Effective Date:

(a) Organization. It is a corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

(b) Authority. It has full right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement, it has the right to grant to the other the licenses and sublicenses granted pursuant to this Agreement, and this Agreement and the performance by such Party of this Agreement do not violate such Party's charter documents, bylaws or other organizational documents.

(c) Consents. Except for any Regulatory Approvals, Regulatory Materials, manufacturing approvals or similar approvals necessary for the Development, Manufacture or Commercialization of Licensed Products, all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons required to be obtained by it in connection with the execution, delivery and performance of this Agreement have been obtained.

(d) No Conflict. It is not under any obligation, contractual or otherwise, to any Person that would materially affect the diligent and complete fulfillment of obligations under this Agreement and the execution and delivery of this Agreement by such Party, and the performance of such Party's obligations under this Agreement (as contemplated as of the Execution Date) and the licenses and sublicenses to be granted by such Party pursuant to this Agreement (i) do not conflict with or violate any requirement of Laws applicable to such Party, (ii) do not conflict with or violate any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party, and (iii) do not conflict with, violate, breach or constitute a default under, or give rise to any right of termination, cancellation or acceleration of, any contractual obligations of such Party or any of its Affiliates.

(e) Enforceability. This Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms, subject to the general principles of equity and subject to bankruptcy, insolvency, moratorium, judicial principles affecting the availability of specific performance and other similar Laws affecting the enforcement of creditors' rights generally.

10.2 Additional Representations, Warranties and Covenants of OncoC4. OncoC4 represents, warrants or covenants to BioNTech, as applicable, that, as of the Execution Date and the Effective Date:

(a) Licensed Patents. All Licensed Patents existing as of the Execution Date are listed on Schedule 1.68. Except as set forth on Schedule 1.68, OncoC4 is either the sole and exclusive owner of or has sufficient rights to grant the rights licensed to BioNTech hereunder with respect to such Licensed Patents, all of which are free and clear of any claims, liens, charges or encumbrances (subject to the Upstream Agreements, where applicable). To OncoC4's knowledge, all Licensed Patents have been filed and prosecuted in good faith in the patent offices in accordance with applicable Laws.

(b) Listed Patents. As of the Execution Date and the Effective Date, the Listed Patents are the only Licensed Patents and are the only Patents Controlled by OncoC4 or any Affiliate of OncoC4 that Claim a Licensed Compound or Licensed Product. As of the Execution Date and the Effective Date, OncoC4 Controls the Listed Patents with respect to Licensed Compound and Licensed Product. The issued Listed Patents are to the best of OncoC4's knowledge valid and enforceable; the pending Listed Patents have been prosecuted in good faith and in accordance with all legal duties of the applicant imposed by patent Laws.

(c) Third Party Challenges. To OncoC4's knowledge, there are no claims, judgments, or settlements against, or amounts with respect thereto, made against OncoC4 or any of its Affiliates relating to the Licensed Patents or the Licensed Know-How. No claim or litigation has been received by OncoC4 or its Affiliates or, to OncoC4's knowledge, threatened by any Person (i) alleging that the Licensed Patents are invalid or unenforceable, (ii) challenging OncoC4's Control of the Licensed Patents (i.e., alleging that a Third Party has a right or interest in or to the Licensed Patents or Licensed Know-How) or (iii) alleging misappropriation of the Know-How of any Third Party used in the Development, Manufacture or Commercialization of Licensed Products by or on behalf of OncoC4 prior to the Effective Date.

(d) Non-Infringement of Third Party IP. To OncoC4's knowledge, the (i) Development and Manufacture of the Licensed Compound and Licensed Product, as conducted by OncoC4 and its Affiliates prior to the Effective Date did not infringe any Patent or misappropriate any Know-How of any Person (in the case of pending Patents, evaluating them as if issued) and (ii) Commercialization of Licensed Compound and Licensed Product as contemplated in the CDP as of the Effective Date will not infringe the Patent of any Third Party. No written claim of infringement or alleged infringement of the Patents that is Controlled by or misappropriation of the Know-How that is Controlled by any Third Party has been received by OncoC4, or to OncoC4's knowledge, threatened, against OncoC4 or any of its Affiliates with respect to the Development or Manufacture of the Licensed Compound or Licensed Product. To OncoC4's knowledge, no Patents owned by a Third Party currently Claim Licensed Compound or Licensed Product, nor their use in any field.

(e) No Infringement Notices to Third Parties. OncoC4 has not given written notice to any Third Party asserting infringement by such Third Party of all or any portion of the Licensed Patents and OncoC4 is not aware of any such infringement.

(f) No Non-Suit Agreements. OncoC4 has not entered into any agreement with a Third Party pursuant to which OncoC4 has agreed not to pursue any infringement by such Third Party of the Licensed Patents.

(g) Absence of Litigation. Except as otherwise disclosed to BioNTech prior to the Execution Date, there are no judgments or settlements against or owed by OncoC4 or its Affiliates, or, to OncoC4's knowledge, pending litigation against OncoC4 or its Affiliates, or litigation threatened against OncoC4 or its Affiliates, in each case, related to any Listed Patents, Licensed Know-how, Licensed Compound or Licensed Product, including any such litigation relating to any Regulatory Materials Controlled by OncoC4 or its Affiliates as of the Execution Date and the Effective Date.

(h) Inventors. Each Person who has or has had any ownership rights in or to any Licensed Patents purported to be owned solely by OncoC4, has assigned and has executed an agreement assigning its entire right, title, and interest in and to such Licensed Patents to OncoC4.

(i) Upstream Agreements. The Upstream Agreements are in full force and effect in accordance with their terms; OncoC4 is not in breach of any Upstream Agreement and knows of no breach of any Upstream Agreement by the other party(ies) thereto; and except as set forth on Schedule 1.105, OncoC4 has neither sent, provided, nor received any notice of breach or intent to terminate any Upstream Agreement. The copies of the Upstream Agreements made available to BioNTech by OncoC4 in due diligence in connection with this Agreement were true, accurate and complete, including all amendments thereto. During the Term, OncoC4 will not knowingly breach any Upstream Agreement, will not terminate any Upstream Agreement, and will not modify or amend any Upstream Agreement in any manner that would limit, restrict or otherwise adversely affect in any material respect the rights granted to BioNTech hereunder, in each case, without obtaining BioNTech's prior written consent. During the Term, OncoC4 will not exercise, waive, release, or assign any rights under any Upstream Agreement in any manner that would limit, restrict or otherwise adversely affect in any material respect the rights granted to BioNTech hereunder, in each case, without obtaining BioNTech's prior written consent. Except as set forth on Schedule 10.2(i), OncoC4 and its Affiliates are not parties to any agreement with a Third Party with respect to Licensed Compounds, Licensed Products, Licensed Patents or Licensed Know-How, that is not included in the Upstream Agreements, other than (i) routine agreements relating to Clinical Trials entered into by OncoC4 or its Affiliates in the ordinary course of business (including ordinary course agreements with clinical investigators), (ii) routine confidentiality and non-disclosure agreements entered into by OncoC4 or its Affiliates in the ordinary course of business, and (iii) routine assignment agreements with employees that fully and completely assign rights in Licensed Patents or Licensed Know-How to OncoC4 and impose no limitations, restrictions, terms, or conditions that would in any way limit OncoC4's Control thereof; *provided*, that OncoC4 shall be responsible for any and all payments to such employees pursuant to any such agreement.

(j) ***. All matters and disputes between ***, on the one hand, and OncoC4 (either directly or as successor in interest to ***) or any of OncoC4's Affiliates, on the other hand, related in any way to the Listed Patents and Licensed Know-How have been fully and finally settled and all settlement and other agreements related to such matters and disputes are included in the Upstream Agreements. Aside from the Upstream Agreements and the agreements set forth on Schedule 10.2(j), there are no other agreements between ***, on the

one hand, and OncoC4 (either directly or as successor in interest to [***]) or any of OncoC4's Affiliates, on the other hand. [***] has not asserted any cause of action against OncoC4, any of its Affiliates, nor, to OncoC4's knowledge, any of the named inventors on the Listed Patents, that has not been fully and finally settled by one or more Upstream Agreements, and there are no other persons who should be named on the Listed Patents, under applicable patent Laws, who have an obligation to assign their interests in the Listed Patents to [***].

(k) [***].

(i) All license and other agreements between [***], on the one hand, and OncoC4 (either directly or as successor in interest to [***]) or any of OncoC4's Affiliates, on the other hand, related to Licensed Compound(s), Licensed Product(s), any component of either of the foregoing (other than an Other Active), or the manufacturing process for any Licensed Compound(s), Licensed Product(s), or any component of either of the foregoing (including any cell lines or other biological materials used in such a process, including those that are proprietary to [***] or any [***] Affiliate) are set forth on Schedule 10.2(k).

(ii) OncoC4 shall use Commercially Reasonable Efforts to amend or receive a written waiver, or cause their Affiliate to receive such written waiver, under the [***] License, as soon as reasonably practicable, and in any event within [***] months, following the Effective Date, to allow for sublicensing through multiple tiers thereunder and the transfer of the licensed cell line to a Third Party manufacturer. In the event that OncoC4 or its Affiliate cannot obtain such amendment or written waiver, at BioNTech's election, BioNTech may either (A) enter into a direct license with [***] or (B) request that OncoC4 or its Affiliate promptly grant (and OncoC4 or its Affiliate shall so promptly grant) a direct (sub)license under the [***] License to any Third Party reasonably requested by BioNTech in accordance with the terms of the [***] License in order to allow BioNTech to complete a technology transfer or otherwise exercise its rights hereunder. In the event that BioNTech elects to enter into a direct license with [***] pursuant to subclause (A) (i.e., in the event that OncoC4 cannot obtain an amendment or written waiver under the [***] License to allow for sublicensing through multiple tiers thereunder and the transfer of the licensed cell line to a Third Party manufacturer), such direct license shall be deemed a necessary Third Party license pursuant to Section 7.7(a) and any payments thereunder would be deductible against royalties in accordance with Section 7.7(a).

(iii) Notwithstanding Section 7.13, royalty payments to [***] under the [***] License and Technology Transfer costs payable to [***] in accordance with Section 5.2(a) will be shared [***] between BioNTech and OncoC4.

(l) The [***] Agreement.

(i) The clinical trial [***] conducted pursuant to the [***] Agreement (the "[***]") (A) would not reasonably be expected to adversely impact the Joint Development Program hereunder and (B) no results from such clinical trial are available as of the Execution Date and the Effective Date.

(ii) As soon as reasonably practicable following the Effective Date, OncoC4 shall be permitted to disclose BioNTech's identity with respect to this Agreement and the [***] to [***] and OncoC4 shall use Commercially Reasonable Efforts to obtain a written

waiver or amendment of the [***] Agreement to enable OncoC4 to (A) share the Joint Clinical Data (as defined in the [***] Agreement) thereunder with BioNTech and (B) keep BioNTech reasonably apprised of any planned patent filings under the [***] Agreement. Notwithstanding any other provision of this Agreement, OncoC4 shall be responsible for [***] of all Joint Development Costs associated with the [***] until such time that BioNTech has obtained access to such Joint Clinical Data. Promptly following the execution of any such waiver or amendment of the [***] Agreement, OncoC4 will provide a copy thereof to BioNTech along with a copy of the [***] Agreement.

(iii) [***]

(m) Compliance. OncoC4 will and will cause its Affiliates to comply in all material respects with all applicable Laws in exercising its rights and fulfilling its obligations under this Agreement. Without limiting the foregoing, OncoC4 will conduct its Development, Manufacturing and, where applicable and subject to Section 5.3(d), Commercialization activities relating to the Licensed Compound and Licensed Product(s) in accordance with applicable Laws (including data privacy Laws, current international regulatory standards, and including, as applicable, GMP, GLP and GCP), and will cause all applicable contractors hereunder to comply with such applicable Laws.

(n) Data. OncoC4 has accurately and completely disclosed to BioNTech all material data known OncoC4 with respect to Licensed Compounds and Licensed Products. The data provided by OncoC4 to BioNTech in due diligence in connection with this Agreement prior to the Execution Date and the Effective Date are accurate and complete in all material respects and OncoC4 has not omitted to include in such due diligence disclosures any data or information necessary to understand or make not misleading the data and information that were disclosed in due diligence.

(o) [***] Patents. Following the Effective Date, OncoC4 shall not, directly or indirectly, Prosecute outside the United States any Patent that was licensed to OncoC4 pursuant to the [***] License.

(p) Record of Ownership. For any Listed Patents owned by OncoC4 or an Affiliate of OncoC4 for which the public record reflects as of the Effective Date a record owner that is not either (i) OncoC4 and/or (ii) an Affiliate of OncoC4, including all such Listed Patents that as of the Effective Date reflect [***] and/or any other [***] entity as the record owner, OncoC4 shall cause itself and/or its Affiliate to be properly recorded as the record owner in the public record in accordance with applicable requirements of Law and procedures of the relevant patent office(s), as promptly as practicable, and shall provide evidence of such recording to BioNTech promptly thereafter.

(q) No Government Funding. Except as set forth on Schedule 10.2(q), the inventions claimed or covered by the Licensed Patents (i) were not conceived, discovered, developed, or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof, (ii) are not a "subject invention" as that term is described in 35 U.S.C. § 201(f), and (iii) are not otherwise subject to the provisions of the 35 U.S.C. §§ 200-212.

10.3 Additional Representations, Warranties and Covenants of BioNTech. BioNTech represents, warrants and covenants to OncoC4 that, as of the Execution Date and the Effective Date:

(a) BioNTech will and will ensure that its Affiliates and Sublicensees comply in all material respects with all applicable Laws in exercising their rights and fulfilling their obligations under this Agreement. Without limiting the foregoing, BioNTech will conduct its Development, Manufacturing and Commercialization activities relating to the Licensed Compound and Licensed Product(s) in accordance with applicable Laws (including data privacy Laws, current international regulatory standards, and including, as applicable, GMP, GLP and GCP), and will cause all permitted contractors and Sublicensees hereunder to comply with such applicable Laws.

(b) Without limiting the generality of Section 10.3(a), BioNTech will comply with all applicable Laws concerning bribery, money laundering, or corrupt practices or which in any manner prohibit the giving of anything of value to any official, agent, or employee of any government, political party, or public international organization, candidate for public office, health care professional, or to any officer, director, employee, or representative of any other organization specifically including the U.S. Foreign Corrupt Practices Act, and the UK Bribery Act, in each case, in connection with the activities conducted pursuant to this Agreement. BioNTech will require any contractors, Sublicensees, or other Persons that provide services to BioNTech in connection with this Agreement to comply with BioNTech's obligations under this Section 10.3(b).

10.4 No Debarment. Each Party represents and warrants that neither it nor any of its or its Affiliates' employees or agents performing under this Agreement has ever been, or is currently: (a) debarred under 21 U.S.C. § 335a or by any Regulatory Authority; (b) excluded, debarred, suspended, or otherwise ineligible to participate in federal health care programs or in federal procurement or non-procurement programs; (c) listed on the FDA's Disqualified and Restricted Lists for clinical investigators; or (d) convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. Each Party further covenants that if, during the Term of this Agreement, it becomes aware that it or any of its or its Affiliates' employees or agents performing under this Agreement is the subject of any investigation or proceeding that could lead to that Party becoming a debarred entity or individual, an excluded entity or individual or a convicted entity or individual, such Party will promptly notify the other Party.

10.5 Investigations. Each Party agrees to provide reasonable cooperation in any investigation that may be conducted by or on behalf of the other Party related to business in connection with this Agreement. Upon notice of an intended investigation, the Party receiving such notice will provide, in a reasonable time, to the other Party or to a Third Party engaged by such other Party: (a) access to the relevant persons; and/or (b) access to relevant documents and data (e.g., invoices and requests for expense reimbursement, supporting receipts and substantiation, and original entry records for charges and payments).

10.6 No Other Warranties. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE X, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR

OTHERWISE, INCLUDING WARRANTIES OF TITLE, NON-INFRINGEMENT OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY WITH RESPECT TO THE LICENSED PRODUCT, VALIDITY, ENFORCEABILITY, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. WITHOUT LIMITING THE FOREGOING, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT EITHER PARTY WILL BE ABLE TO SUCCESSFULLY ADVANCE THE LICENSED COMPOUND OR ANY LICENSED PRODUCT, OR DEVELOP, OBTAIN REGULATORY APPROVAL FOR, MANUFACTURE OR COMMERCIALIZE THE LICENSED COMPOUND OR ANY LICENSED PRODUCT, OR, IF COMMERCIALIZED, THAT ANY PARTICULAR SALES LEVEL OR PROFIT OF ANY LICENSED PRODUCT WILL BE ACHIEVED.

ARTICLE XI INDEMNIFICATION; DAMAGES

11.1 Indemnification by OncoC4. OncoC4 will defend, indemnify and hold harmless BioNTech, its Affiliates and their respective directors, officers, employees and agents (each, a “**BioNTech Indemnified Party**”) from, against and in respect of any and all Losses incurred or suffered by any BioNTech Indemnified Party to the extent resulting from Actions brought by a Third Party (a “**Third Party Action**”) arising out of: (a) any breach by OncoC4 or its Affiliates or sublicensees under this Agreement; (b) the negligence or intentional misconduct of OncoC4 or any of its Affiliates, sublicensees, or contractors, or any of their respective directors, officers, employees and agents, in performing OncoC4’s obligations under this Agreement; (c) any claims, including claims for payment owed or alleged to be owed by OncoC4, under (i) any agreement between OncoC4 and a Third Party entered into prior to the Effective Date to the extent such claims relate to pre-Effective Date activities or result from or relate to the terms of this Agreement (for clarity, not including the Exploitation by or on behalf of the Parties of the Licensed Compound or Licensed Products after the Effective Date as contemplated by this Agreement) or (ii) an Upstream Agreement, in each case ((i) and (ii)), including any such claims related to joint ownership over intellectual property rights; or (d) the [***] License; *provided, however*, that OncoC4’s obligations pursuant to this Section 11.1 will not apply to the extent such Losses result from any events or activities described in Section 11.2 for which BioNTech has an obligation to indemnify any OncoC4 Indemnified Party. In addition, OncoC4 will indemnify BioNTech Indemnified Parties for [***] of their Losses arising out of Third Party Actions resulting from the Joint Development Program, but excluding those Third Party Actions arising out of the causes set forth in Section 11.1(a) or (b) or Section 11.2(a), (b), or (c) (“**Shared CDP Liability Claims**”).

11.2 Indemnification by BioNTech. BioNTech will defend, indemnify and hold harmless OncoC4, its Affiliates and their respective directors, officers, employees and agents (each, a “**OncoC4 Indemnified Party**”) from, against and in respect of any and all Losses incurred or suffered by any OncoC4 Indemnified Party to the extent resulting from Third Party Actions arising out of: (a) any breach by BioNTech or its Affiliates or Sublicensees under this Agreement; (b) the negligence or intentional misconduct of BioNTech or any of its Affiliates, Sublicensees, or contractors, or any of their respective directors, officers, employees and agents, in performing BioNTech’s obligations or exercising BioNTech’s rights under this Agreement, or (c) BioNTech’s or its Affiliates’ or Sublicensees’ Exploitation (other than as part of the Joint Development Program) of the Licensed Compound or Licensed Products in the Field in the

Territory; *provided, however*, that BioNTech's obligations pursuant to this Section 11.2 will not apply to the extent such Losses result from any events or activities described in Section 11.1 for which OncoC4 has an obligation to indemnify any BioNTech Indemnified Party. In addition, BioNTech will indemnify, defend and hold harmless OncoC4 Indemnified Parties for [***] of their Losses arising out of Third Party Actions resulting from the Joint Development Program, but excluding those Third Party Actions arising out of the causes set forth in Section 11.1(a) or (b) or Section 11.2(a), (b), or (c).

11.3 Claims for Indemnification.

(a) Notice. An Indemnified Party entitled to indemnification under Section 11.1 or Section 11.2 will give prompt written notification to the Indemnifying Party from whom indemnification is sought of the commencement of any Action by a Third Party for which indemnification may be sought (a "**Third Party Claim**") or, if earlier, upon the assertion of such Third Party Claim by a Third Party; *provided, however*, that failure by an Indemnified Party to give notice of a Third Party Claim as provided in this Section 11.3(a) will not relieve the Indemnifying Party of its indemnification obligation under this Agreement, except and only to the extent that such Indemnifying Party is materially prejudiced as a result of such failure to give notice.

(b) Defense. Within [***] Business Days after delivery of a notice of any Third Party Claim in accordance with Section 11.3(a), the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such Third Party Claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party may control such defense (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not to be unreasonably withheld). The Party not controlling such defense may participate therein at its own expense.

(c) Cooperation. The Party controlling the defense of any Third Party Claim will keep the other Party advised of the status and material developments of such Third Party Claim and the defense thereof and will reasonably consider recommendations made by the other Party with respect thereto. The other Party will reasonably cooperate with the Party controlling such defense and its Affiliates and agents in defense of the Third Party Claim, with all out-of-pocket costs of such cooperation to be borne by the Party controlling such defense.

(d) Settlement. The Indemnified Party will not agree to any settlement of such Third Party Claim without the prior written consent of the Indemnifying Party, which consent will not be unreasonably withheld, conditioned or delayed. The Indemnifying Party will not, without the prior written consent of the Indemnified Party, which will not be unreasonably withheld, conditioned or delayed (unless such compromise or settlement involves (i) any admission of legal wrongdoing by the Indemnified Party, (ii) any payment by the Indemnified Party that is not indemnified under this Agreement, or (iii) the imposition of any equitable relief against the Indemnified Party (in which case, (i) through (iii), the Indemnified Party may withhold, condition or delay its consent to such settlement in its sole discretion)), agree to any settlement of such Third Party Claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with

respect thereto or that imposes any liability or obligation on the Indemnified Party (other than a monetary obligation on the Indemnifying Party).

(e) **Mitigation of Loss.** Each Indemnified Party will take and will procure that its Affiliates take all such reasonable steps and actions as are necessary or as the Indemnifying Party may reasonably require in order to mitigate any Third Party Claims (or potential losses or damages) under this ARTICLE XV. Nothing in this Agreement will or will be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

11.4 **Insurance.** Each Party, at its own expense, will maintain liability insurance in an amount consistent with industry standards during the Term, but in no event will such insurance be in an aggregate amount less than [***] per occurrence/annual aggregate during the Term. In addition, during the Commercialization of any Licensed Product and for a period of at least [***] years thereafter, BioNTech will maintain product liability insurance in accordance with industry standards. Each Party will maintain Clinical Trial insurance in compliance with all applicable Laws pertaining to the jurisdictions in which such Clinical Trials are conducted. Each Party will provide certificate(s) of insurance evidencing such coverages to the other Party upon written request.

ARTICLE XII LIMITATION OF LIABILITY

12.1 **No Consequential or Punitive Damages.** EXCEPT AS SET FORTH IN SECTION 12.2, NEITHER PARTY NOR ANY OF ITS AFFILIATES WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS OR THE PERFORMANCE OF ITS OBLIGATIONS HEREUNDER, INCLUDING ANY LOST PROFITS ARISING OUT OF THIS AGREEMENT, IN EACH CASE, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES.

12.2 **Exclusion from Liability Limitation.** THE LIMITATIONS AND DISCLAIMER SET FORTH IN SECTION 12.1 WILL NOT APPLY TO A CLAIM: (A) FOR GROSS NEGLIGENCE OR WILLFUL MISCONDUCT; (B) FOR A BREACH OF SECTION 8.1 OR ARTICLE IX; OR (C) FOR INDEMNIFIABLE LOSSES PURSUANT TO SECTION 11.1 OR SECTION 11.2 TO THE EXTENT SUCH DAMAGES ARE AWARDED TO A THIRD PARTY.

ARTICLE XIII TERM AND TERMINATION

13.1 **Term.** Unless terminated earlier in accordance with this ARTICLE XIII, and except with respect to ARTICLE I, ARTICLE XIV, ARTICLE XV, and Sections 2.6, 9.1, 9.2, 9.3, 10.1, 10.2, 10.3, 10.6 and 13.1, all of which shall become effective on the Execution Date, this Agreement will become effective as of the Effective Date and will continue in full force and effect until the last to expire Royalty Term in all countries in the Territory for all Licensed Products (the “**Term**”). If at any time there are no longer any Licensed Patents nor [***]

pending or issued, and no Royalty Term is then in effect in any country with respect to any Licensed Product, the Term shall expire.

13.2 Paid-Up License Upon Expiration of Royalty Term. Upon the expiration of the Royalty Term for a Licensed Product in a given country in the Territory, the Exclusive License granted to BioNTech pursuant to Section 2.1(a) will become perpetual, irrevocable, non-exclusive, fully paid-up, and royalty free with respect to such Licensed Product in such country.

13.3 Early Termination.

(a) Termination for Material Breach. Upon any material breach of this Agreement by OncoC4 or BioNTech (the Party so allegedly breaching, the “**Allegedly Breaching Party**”), the other Party (the “**Non-Breaching Party**”) will have the right, but not the obligation, to terminate this Agreement in its entirety by providing (i) at least [***] days’ written notice to the Allegedly Breaching Party with respect to any breach of any payment obligation under this Agreement or (ii) at least [***] days’ written notice to the Allegedly Breaching Party with respect to any other breach, which notice will, in each case (A) expressly reference this Section 13.3(a) and state that it is a notice of material breach under this Section 13.3(a), (B) reasonably describe the alleged breach which is the basis of such termination, and (C) clearly state the Non-Breaching Party’s intent to terminate this Agreement if the alleged breach is not cured within the applicable cure period. For material breaches not capable of cure within [***] days that may be alleged, but excluding breaches in the form of a failure to pay an amount due or a breach of Section 2.6, 3.2(e) or 15.17, the [***] day cure period shall be extended to such longer reasonable period as in which it is possible for the Allegedly Breaching Party to cure if it provides written notice within the [***] days of its intent and plan to cure and subsequently proceeds to use Commercially Reasonable Efforts to carry out such plan (as it may be updated based upon circumstances subsequently encountered); *provided*, that such extended cure period shall not exceed [***] days following the notice of breach under this Section 13.3(a) and following such [***] day period the Non-Breaching Party shall have the right, but not the obligation, to terminate this Agreement on at least [***] days’ prior written notice. The termination, if not disputed, will become effective at the end of the notice period (or if applicable such extended cure period) unless the Allegedly Breaching Party cures such breach during such notice period; *provided, however*, that (i) Non-Breaching Party may, by notice to the Breaching Party, propose a later date for such termination in order to facilitate an orderly transition of activities relating to Licensed Products in which case Section 13.4(c) shall apply *mutatis mutandis*, and (ii) if the termination is disputed, then the notice and cure periods under this Section 13.3(a) and the right of the Parties to terminate this Agreement shall be tolled, and otherwise this Agreement and the Parties’ rights hereunder (including the Exclusive License and if still in effect the Option) shall remain in full force and effect, in each case, pending the outcome of dispute resolution in accordance with this Agreement, at which time this Agreement either will or will not terminate based upon the results of the dispute resolution (i.e., in accordance with the arbitral award). In no event shall this Agreement be terminated by a termination under this Section 13.3(a) while dispute resolution with respect to whether a Party is entitled to terminate under this Section 13.3(a) is ongoing.

(b) Termination by BioNTech. BioNTech will have the right to terminate this Agreement in its entirety for convenience, for any reason or for no reason, at will, on no less than [***] months’ prior written notice to OncoC4.

(c) Termination for Bankruptcy. This Agreement may be terminated, to the extent permitted by applicable Laws, by either Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; *provided, however*, that in the case of any involuntary bankruptcy, reorganization, liquidation or receivership proceeding such right to terminate will only become effective if the Party subject to such proceeding consents to the involuntary bankruptcy or such proceeding is not dismissed within ninety (90) days after the filing thereof.

13.4 Effects of Termination for BioNTech Fault or by BioNTech At Will. The following shall be the effects of termination only for the following terminations: (X) by OncoC4 under Section 13.3(a) (BioNTech uncured material breach), Section 13.3(c) (BioNTech bankruptcy) or (Y) by BioNTech under Section 13.3(b) (at will).

(a) Effects of Termination Generally. Upon the effective date of termination, the Parties' rights, licenses, and obligations under this Agreement will terminate and neither Party will have any further rights or obligations under this Agreement from and after the effective date of termination, except as set forth in this Section 13.4 and Sections 13.6-13.8.

(b) Reversion of Rights. All rights that OncoC4 granted hereunder to BioNTech pursuant to the Exclusive License for Licensed Compounds and Licensed Products will terminate and revert to OncoC4. All Licensed Single Products and Combination Products, provided that such Combination Products were Developed under the CDP that on or prior to the effective date of termination were undergoing active Development or Commercialization are "**Reversion Products**;" *provided, however*, that the Reversion Products shall exclude all BioNTech Products or Combination Products containing BioNTech Product(s).

(c) Winding Down of Activities. If there are any on-going Development or Commercialization activities with respect to Licensed Compounds or Licensed Products at termination of this Agreement, the Parties will negotiate in good faith and adopt a plan to wind-down, discontinue and terminate such activities in an orderly fashion or, at OncoC4's election in the case of Reversion Product(s), promptly transition such activities to OncoC4 or its designee, in each case, with due regard for patient safety and the rights of any subjects that are participants in any Clinical Trials, and take any actions the Parties deem reasonably necessary or appropriate to avoid any human health or safety problems and comply with all applicable Laws.

(d) [***]

(e) [***]

(f) Inventory. Upon termination of this Agreement, OncoC4 will have the right to purchase all of BioNTech and its Affiliates' remaining inventory of Reversion Products held as of the effective date of termination of this Agreement at a price equal to BioNTech's Fully Burdened Manufacturing Cost (excluding any portion of such costs previously paid by OncoC4 through its payment of its share of Joint Development Costs).

(g) Further Assistance. At OncoC4's sole cost and expense, BioNTech will (i) provide any other assistance or take any other actions, in each case reasonably requested by

OncoC4, as necessary to transfer to OncoC4 the Development, Manufacture or Commercialization of the Reversion Product(s) and (ii) execute all documents as may be reasonably requested by OncoC4 in order to give effect to this Section 13.4.

(h) Third Party Agreements. Upon OncoC4's request, BioNTech agrees to discuss in good faith for a reasonable period of time (not less than [***] days) whether BioNTech would be willing to assign to OncoC4, in whole or in part, BioNTech's and its Affiliates' right, title and interest in and to any agreements between BioNTech or any of its Affiliates and Third Parties that relate to the Development, Manufacture or Commercialization of any Reversion Product(s).

(i) Return of Confidential Information. Within [***] Business Days after the effective date of termination (but not expiration) of this Agreement in its entirety, each Party will, and cause its Affiliates to (i) destroy, all tangible items solely comprising, bearing or containing any Confidential Information of the other Party that are in such first Party's or its Affiliates' possession or Control, and provide written certification of such destruction, or (ii) return all tangible items of the other Party's Confidential Information to such other Party, as such other Party may direct, at the first Party's expense; *provided, however*, that in any event, (A) each Party may retain copies of the Confidential Information of the other Party to the extent necessary to perform its obligations or exercise its rights that survive termination of this Agreement; (B) each Party may retain one copy of the Confidential Information of the other Party for its legal archives; and (C) each Party may retain Confidential Information contained in electronically stored backup files or other media created by or on behalf of the receiving Party in accordance with its standard or routine archiving and back-up procedures.

(j) Cooperation. Each Party will cause its Affiliates, Sublicensees and contractors to comply with the obligations in this Section 13.4.

(k) Sublicensee Rights. In the event of termination by OncoC4 pursuant to Section 13.3(a), any Sublicensee of rights to Mono/PD-1 Combinations, only, that is in good standing as of the effective date of termination shall have the right, by written notice to OncoC4 given within [***] days after the date that such Sublicensee learns of the termination of this Agreement, to become a direct licensee of OncoC4 on terms and conditions substantially similar to those set forth in this Agreement, but only for the scope of Sublicense rights that were granted to such Sublicensee in its Sublicense and the scope of Reversion Products rights that are returned or granted to OncoC4 hereunder, and only to the extent BioNTech assigns, licenses and transfers to OncoC4 all rights, assets and information as is necessary in order for OncoC4 to fully perform and fully comply with any and all terms and conditions of such Sublicense in all respects (large and small).

13.5. Effects of Termination for OncoC4 Fault. The following shall be the effects of termination only for the following terminations: by BioNTech under Section 13.3(a) (OncoC4 uncured material breach) or 13.3(c) (OncoC4 bankruptcy):

- (a) The Exclusive License and (if still in effect) the Option shall survive (in accordance with its terms).

(b) All rights of reference and access granted BioNTech in or in accordance with this Agreement shall survive.

(c) All diligence obligations of BioNTech shall terminate and shall not survive, and BioNTech shall have no further diligence obligations in relation to Licensed Compounds and Licensed Products, or of any kind, express or implied, notwithstanding anything in this Agreement, at law, or equity.

(d) Subject to Section 13.6 and Section 13.8, BioNTech's obligations to pay Development Milestone Payments shall terminate and shall not survive termination of this Agreement, but BioNTech's obligations to pay royalties and Sales Milestone Payments hereunder in due course as they come due shall survive, except that all royalty payment and Sales Milestone Payment amounts that would have been due in the absence of the termination shall be reduced by [***] (and, for clarity, Section 7.7(f) shall not negate such [***] reduction; rather in this circumstance, Section 7.7(f) shall apply to calculate the amount that would have been due in the absence of the termination, and the reduction under this Section 13.5(d) shall apply after that).

(e) OncoC4 shall have no further right or obligation (except as expressly provided in this Section 13.5) to participate in the Joint Development Program nor the activities that were provided for in the CDP, and OncoC4 shall have no further responsibility for any portion of Joint Development Costs incurred following, or otherwise allocable to any activity conducted after, the effective date of termination of this Agreement, *provided, however*, that OncoC4 shall continue to be responsible for its otherwise applicable share of Joint Development Costs, subject to the CDP and Joint Development Budget last approved by the JSC in accordance with this Agreement (but not pursuant to an exercise by BioNTech of its final decision-making authority after a notice of termination) as of the effective date of termination, during a [***] wind-down period following the effective date of termination, and BioNTech shall be entitled to offset OncoC4's share of such costs against payments due hereunder pursuant to BioNTech's surviving royalty payment obligations. OncoC4 shall reasonably cooperate with BioNTech in any transition activities reasonably requested by BioNTech to transfer activities that OncoC4 or its Affiliate were performing under the Joint Development Program as of the effective date of termination to BioNTech or its Affiliate.

(f) The Parties' obligations under ARTICLE IX shall survive for [***] years after the effective date of termination, and for clarity information disclosed by either Party in connection with its surviving rights and obligations under this Agreement may qualify as Confidential Information as defined herein.

(g) Effective upon the effective date of termination, OncoC4 hereby assigns to BioNTech all right, title, and interest otherwise held by OncoC4 and its Affiliates in the [***] and Know-How Controlled by OncoC4 or its Affiliate that is necessary for BioNTech to Exploit Licensed Products that were actively being Developed or Commercialized at the time of the termination of this Agreement (but not including any rights with respect to any Other Active contained in a Combination Product) (and solely with respect to the Know-How, limited to the manner in which the Licensed Products were being Developed or Commercialized at the time), all Regulatory Materials in respect of such Licensed Products otherwise held by OncoC4 and its Affiliates, all inventories of such Licensed Products and Licensed Compounds for use therein

(but not including any Other Active contained in a Combination Product), and all contracts (to the extent assignable) for the Manufacture or Development of such Licensed Products and Licensed Compounds for use therein (but not including any Other Active contained in a Combination Product) that BioNTech elects by written notice after having [***] days to review such contracts to take assignment of (and OncoC4 shall provide copies of such contracts that BioNTech has the right to elect assignment of, subject to applicable confidentiality restrictions, within [***] days after the effective date of termination). OncoC4 shall execute and deliver to BioNTech any documents and instruments reasonably requested by BioNTech to evidence or record such assignment or to file for, prosecute, cause to issue, or enforce any of the assigned rights and/or properties, in each case, in accordance with this Section 13.5(g).

(h) BioNTech shall have the exclusive [***].

(i) OncoC4's obligations hereunder to maintain in full force and effect and fully perform the Upstream Agreements, including making all payments due thereunder, as described in Section 2.7, shall survive, but only to the extent relating to Licensed Products actively Developed or Commercialized at the time of the termination of this Agreement. In addition, upon BioNTech's request, on an Upstream Agreement-by-Upstream Agreement basis, OncoC4 agrees to discuss in good faith for a reasonable period of time (not less than [***] days) whether OncoC4 would be willing to assign to BioNTech OncoC4's and its Affiliates' right, title and interest in and to any such Upstream Agreement.

(j) All other rights and obligations of the Parties, except as provided in Sections 13.6 and 13.7, shall terminate.

13.6. Accrued Obligations. Expiration or termination of this Agreement for any reason will not release either Party from any obligation or liability which, on the effective date of such expiration or termination, has already accrued to the other Party or which is attributable to a period prior to such expiration or termination.

13.7. Survival. The provisions set forth in the following Sections, as well as, to the extent applicable, any other Sections or defined terms referred to in such Sections or Articles or necessary to give them effect, will survive any expiration or termination of this Agreement: Sections 4.2, 7.9, 7.10, 7.13, 8.1, 8.2 (solely with respect to Joint Patents) and 8.3 (solely with respect to Joint Patents), 8.5, 8.9, 9.1 (for the time period set forth therein), 9.3, 10.6, 13.2 (solely in the event of expiration and on a Licensed Product-by-Licensed Product and country-by-country basis), 13.4 and 13.5 (each, to the extent applicable), 13.6-13.8 (inclusive); ARTICLE VII (for the time period set forth therein), ARTICLE XI (provided that Section 11.4 shall survive solely for the time period set forth therein), ARTICLE XII, ARTICLE XIV and ARTICLE XV (except for Sections 15.17 and 15.18); and all Schedules or Exhibits that are referenced in a surviving provision. Furthermore, any other provisions required to interpret the Parties' rights and obligations under this Agreement, including applicable definitions in ARTICLE I, will survive to the extent required.

13.8. Non-Exclusive Remedies. All of the effects of termination (for clarity, not expiration) set forth in this ARTICLE XIII are in addition to any other rights and remedies that

may be available to the Parties under this Agreement or applicable Law, and such effects of termination will not be construed to limit any such rights or remedies.

ARTICLE XIV **DISPUTE RESOLUTION**

14.1. **Dispute Resolution; Escalation.** The Parties recognize that disputes as to certain matters arising out of or in connection with this Agreement may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising out of or in connection with this Agreement in an expedited manner by mutual cooperation. To accomplish this objective, except as specified in Section 13.4(d) any and all disputes between the Parties arising out of or in connection with this Agreement (including any dispute or failure to disagree arising at the JSC or dispute regarding Section 15.17) will first be referred to the Senior Officers for resolution and the Senior Officers will attempt to resolve the matter in good faith. If the Senior Officers fail to resolve such matter within fifteen (15) Business Days after the date on which the matter is referred to the Senior Officers (unless a longer period is agreed to by the Parties), then either Party may submit the dispute for final resolution by binding arbitration in accordance with Section 14.2.

14.2. **Arbitration.** Except as set forth in this Section 14.2 or otherwise expressly provided in this Agreement (including matters that expressly require the mutual agreement of the Parties), each dispute, difference, controversy or claim arising in connection with or related or incidental to, or question occurring under, this Agreement or the subject matter hereof that is not resolved pursuant to Section 14.1 within the time from set forth therein will at the written request of either Party be referred to and finally resolved by arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association (the “**Rules**”). Each Party will within [***] Business Days after the institution of the arbitration proceedings appoint one (1) arbitrator and the third arbitrator to be selected by mutual agreement of the two (2) arbitrators appointed by the Parties, and each arbitrator will have significant experience in the biopharmaceutical industry. If the two initial arbitrators are unable to select a third arbitrator within [***] Business Days after the selection of the second arbitrator, then the third arbitrator will be appointed in accordance with the Rules. The foregoing arbitration proceedings may be commenced by either Party by written notice to the other Party. Unless otherwise agreed by the Parties, all such arbitration proceedings will be held in New York, New York; *provided, however*, that proceedings may be conducted by telephone conference call with the consent of the Parties and the arbitrator(s). All arbitration proceedings will be conducted in the English language. The arbitrators will consider grants of equitable relief and orders for specific performance as co-equal remedies along with awards of monetary damages. The arbitrators will have no authority to award punitive damages. The allocation of expenses of the arbitration, including reasonable attorney’s fees, will be determined by the arbitrators, or, in the absence of such determination, each Party will pay its own expenses and will share equally the expenses of the third arbitrator. The Parties hereby agree that the arbitrators have authority to issue rulings and orders regarding all procedural and evidentiary matters that the arbitrators deem reasonable and necessary with or without petition therefore by the Parties as well as the final ruling and judgment. Except for any appeals process provided for by AAA at the time, to which each Party hereby consents, and any court appeals available under applicable law (including New York State and U.S. federal law), all rulings by the arbitrators will be final. Notwithstanding any contrary provision of this Agreement, any Party may seek equitable measures of protection in the

form of attachment of assets or injunctive relief (including specific performance and injunctive relief) in any matter relating to the proprietary rights and interests of either Party from any court of competent jurisdiction. The provisions of this Section 14.2 may be enforced and judgment on the award (including equitable remedies) granted in any arbitration hereunder may be entered in any court having jurisdiction over the award or any of the Parties or any of their respective assets. Except to the extent necessary to confirm an award or as may be required by Laws, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. Nothing in this Section 14.2 will preclude either Party from seeking interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding. Notwithstanding the Parties' agreement to arbitrate, unless the Parties agree in writing in any particular case, claims and disputes between the Parties relating to or arising out of, or for which resolution depends in whole or in part on a determination of the interpretation, scope, validity, enforceability or infringement of, Patents or Trademarks relating to any Licensed Products will not be subject to arbitration under this Agreement, and the Parties may pursue whatever rights and remedies may be available to them under law or equity, including litigation in a court of competent jurisdiction, with respect to such claims and disputes.

14.3. Jury Waiver. EACH PARTY, TO THE EXTENT PERMITTED BY LAW, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY ACTION OR OTHER LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS IT CONTEMPLATES TO ARBITRATE AS SET FORTH IN SECTION 14.2 (ARBITRATION). THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT OR OTHERWISE.

ARTICLE XV **MISCELLANEOUS**

15.1. Assignment; Successors.

(a) Assignment.

(i) General. This Agreement and the rights and obligations of each Party under this Agreement will not be assignable, delegable, transferable, pledged or otherwise disposed of by either Party without the prior written consent of the other Party; provided, however, that either Party may assign or transfer this Agreement together with all of its rights and obligations hereunder, without such consent (but with written notice to the other Party) (A) to an Affiliate or (B) to a successor in interest in connection with the transfer or sale of all or substantially all of its business or assets to which this Agreement relates, or in the event of its merger or consolidation, reorganization or similar transaction, subject to the assignee agreeing in writing to be bound by the terms and conditions of this Agreement. Any assignment in violation of this Section 15.1(a)(i) will be null and void.

(ii) Securitization. Notwithstanding anything to the contrary in Section 15.1(a)(i) or elsewhere in this Agreement, following the earlier of (A) substantial completion by or on behalf of OncoC4 of all material Development activities to be conducted by OncoC4 under the CDP, and (B) the First Commercial Sale of a Licensed Product, OncoC4 may assign to a Third Party its right to receive milestone payments and/or royalty payments owed under ARTICLE VII (such assignment, a “**Securitization Transaction**”) without the prior written consent of BioNTech. In connection with a contemplated Securitization Transaction, OncoC4 may disclose to Third Parties Confidential Information to the extent reasonably necessary to enable the evaluation of the Securitization Transaction opportunity (provided that such Third Parties are under obligations of confidentiality and non-use with respect to such Confidential Information that are no less stringent than those in this Agreement (but of duration customary in confidentiality agreements entered into for a similar purpose)). As part of any consummated Securitization Transaction, OncoC4 may delegate its right to receive royalty reports and to conduct audits under Section 7.6 and Section 7.8 to the counterparty in such Securitization Transaction, and to allow such counterparty to exercise its rights under such Sections, and such delegation, exercise of rights, and disclosure of Confidential Information to any such counterparty (provided that such counterparty (1) is not a BioNTech Competitor and (2) is under obligations of confidentiality and non-use with respect to such Confidential Information that are no less stringent than those in this Agreement (but of duration customary in confidentiality agreements entered into for a similar purpose)) shall not be a breach by OncoC4 of its obligations under this Agreement.

(b) Successors. Any permitted assignment of the rights and obligations of a Party under this Agreement will be binding on, and inure to the benefit of and be enforceable by and against, the successors and permitted assigns of the assigning Party. The permitted assignee or transferee will assume all obligations of its assignor or transferor under this Agreement. Any assignment or attempted assignment by either Party in violation of the terms of this Section 15.1(b) will be null, void and of no legal effect.

(c) Change of Control of OncoC4. Notwithstanding anything herein, neither OncoC4 nor any of its Affiliates will be deemed to Control any Know-How, Patent, Regulatory Material, Regulatory Approval or other property right that is Controlled by a Third Party described in the definition of “Change of Control,” or such Third Party’s Affiliates (other than an Affiliate of OncoC4 existing prior to the Change of Control), (i) prior to the closing of such Change of Control, except to the extent that any such Know-How, Patent, Regulatory Material, Regulatory Approval or other property right was conceived, discovered, developed, reduced to practice, or otherwise made by such Third Party prior to such Change of Control using or incorporating any Know-How, Patent, Regulatory Material, Regulatory Approval or other property right Controlled by OncoC4 or any of its Affiliates existing prior to such Change of Control, or (ii) after such Change of Control to the extent that such Know-How, Patent, Regulatory Material, Regulatory Approval or other property right is conceived, discovered, developed, reduced to practice, or otherwise made by such Third Party or its Affiliates (other than OncoC4 or its Affiliates existing prior to the Change of Control) after such Change of Control without using or incorporating any Know-How, Patent, Regulatory Material, Regulatory Approval or other property right Controlled by OncoC4 or any of its Affiliates existing prior to such Change of Control.

(d) Change of Control of BioNTech. Notwithstanding anything herein, neither BioNTech nor any of its Affiliates will be deemed to Control any Know-How, Patent, Regulatory Material, Regulatory Approval or other property right that is Controlled by a Third Party described in the definition of "Change of Control," or such Third Party's Affiliates (other than an Affiliate of BioNTech existing prior to the Change of Control), (i) prior to the closing of such Change of Control, except to the extent that any such Know-How, Patent, Regulatory Material, Regulatory Approval or other property right was conceived, discovered, developed, reduced to practice, or otherwise made by such Third Party prior to such Change of Control using or incorporating any Know-How, Patent, Regulatory Material, Regulatory Approval or other property right Controlled by BioNTech or any of its Affiliates existing prior to such Change of Control, or (ii) after such Change of Control to the extent that such Know-How, Patent, Regulatory Material, Regulatory Approval or other property right is conceived, discovered, developed, reduced to practice, or otherwise made by such Third Party or its Affiliates (other than BioNTech or its Affiliates existing prior to the Change of Control) after such Change of Control without using or incorporating any Know-How, Patent, Regulatory Material, Regulatory Approval or other property right Controlled by BioNTech or any of its Affiliates existing prior to such Change of Control.

15.2. Choice of Laws. Except as expressly provided herein, this Agreement will be governed by and interpreted under [***], without regard to any conflicts of law principles thereof. Any dispute, controversy, claim or difference of any kind whatsoever arising out of or in connection with this Agreement will be resolved exclusively in accordance with Section 14.2; *provided, however*, that all questions concerning (a) ownership of Patents under this Agreement will be determined in accordance with Section 8.1 and (b) the construction or effect of Patents will be determined in accordance with the Laws of the country or other jurisdiction in which the particular patent or patent application within such Patents has been filed or granted, as the case may be. Any communication or proceedings resulting from disputes under this Agreement will be in English language. The Parties agree to exclude the application to this Agreement of the United Nations Conventions on Contracts for the International Sale of Goods (1980).

15.3. Notices. Any notice or report required or permitted to be given or made under this Agreement by one Party to the other will be in writing and will be deemed to have been delivered (a) upon personal delivery (upon written confirmation of receipt), (b) when received by the addressee, if sent by an internationally recognized overnight courier that maintains records of delivery, or registered or certified mail, postage prepaid, return receipt requested and (c) in the case of notices provided by email (which notice will be followed by an additional notice pursuant to clause (a) or (b) above if the notice is of a default under this Agreement), upon completion of transmission, with transmission confirmed, to the addressee's email address below (or at such other addresses as may have been furnished in writing by a Party to the other as provided in this Section 15.3). For clarity, this Section 15.3 is not intended to govern day-to-day business

communications between the Parties in performing their obligations under the terms of this Agreement.

If to OncoC4:

OncoC4, Inc.
9640 Medical Center Drive
Rockville, MD 20850
Attention: [***]
Email: [***]

with copies (which shall not constitute notice) to:

Goodwin Procter LLP
1900 N Street, NW
Washington, DC 20036
Attention: [***]
Email: [***]

If to BioNTech:

BioNTech SE
Attention: [***]
An der Goldgrube 12
55131 Mainz
Germany
Email: [***]

15.4. Severability. In the event that one or more provisions of this Agreement is held invalid, illegal or unenforceable in any respect, then such provision will not render any other provision of this Agreement invalid or unenforceable, and all other provisions will remain in full force and effect and will be enforceable, unless the provisions that have been found to be invalid or unenforceable will substantially affect the remaining rights or obligations granted or undertaken by either Party. The Parties agree to attempt to substitute for any invalid or unenforceable provision a provision which achieves to the greatest extent possible the economic objectives of the invalid or unenforceable provision.

15.5. Integration. This Agreement, together with all schedules and exhibits attached hereto, constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes all previous arrangements between the Parties with respect to the subject matter hereof, whether written or oral, including, effective as of the Execution Date, the Mutual Non-Disclosure Agreement between the Parties dated [***] (provided that from and after the Execution Date all information disclosed or exchanged under such agreement will be treated as if disclosed hereunder; for clarity such MNDA shall continue to govern the Parties rights and obligations prior to the Effective Date, with respect to the information exchanged thereunder). In the event of a conflict between the CDP or any schedules or attachments to this Agreement, on the one hand, and this Agreement, on the other hand, the terms of this Agreement will govern.

Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement.

15.6. Waivers and Amendments. The failure of any Party to assert a right under this Agreement or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. The exercise by any Party of any right or election under the terms or covenants herein will not preclude or prejudice any Party from exercising the same or any other right it may have under this Agreement, irrespective of any previous action or proceeding taken by the Parties hereunder. Notwithstanding the authority granted to the JSC under this Agreement, (a) no waiver will be effective unless it has been given in writing and signed by the Party giving such waiver, and (b) no provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

15.7. Independent Contractors; No Agency. Neither Party will have any responsibility for the hiring, firing or compensation of the other Party's or such other Party's Affiliates' employees or for any employee benefits with respect thereto. No employee or representative of a Party or its Affiliates will have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on such other Party, without such other Party's written approval. For all purposes, and notwithstanding any other provision of this Agreement, each Party's legal relationship under this Agreement to the other Party will be that of independent contractor, and the relationship between the two Parties will not constitute a partnership, joint partnership, joint venture, or agency, including for all tax purposes, except as otherwise required by applicable Law.

15.8. Affiliates, Sublicensees, and Contractors. To the extent that this Agreement imposes obligations on Affiliates, Sublicensees or contractors of a Party, such Party will cause its Affiliates and its Sublicensees and contractors to perform such obligations, as applicable. Either Party may use one or more of its Affiliates, Sublicensees or contractors to perform its obligations and duties or exercise its rights under this Agreement, solely to the extent permitted and as specified in this Agreement; *provided, however*, that (a) each such Affiliate, Sublicensee or contractor will perform any such obligations delegated to it in compliance with the applicable terms and conditions of this Agreement as if such Affiliate, Sublicensee or contractor were a party hereto, (b) the performance of any obligations of a Party's by its Affiliates, Sublicensees or contractors will not diminish, reduce or eliminate any obligation of such Party under this Agreement, (c) each Party will terminate promptly any contractor, and will give the other Party notice of such termination, in the case of any material breach of this Agreement by a contractor and (d) subject to such Party's assignment to an Affiliate pursuant to Section 15.1, such Party will remain liable under this Agreement for the prompt payment and performance of all of its obligations under this Agreement. Subject to this Section 15.8, if a Party exercises its rights and performs its obligations under this Agreement through one or more of its Affiliates, "OncoC4" will be interpreted to mean "OncoC4 or its Affiliates" and "BioNTech" will be interpreted to mean "BioNTech or its Affiliates" where necessary to give each Party's Affiliates the benefit of the rights provided to such Party in this Agreement and the ability to perform its obligations under this Agreement.

15.9. No Third Party Beneficiary Rights. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and

their successors and permitted assigns, and they will not be construed as conferring any rights on any other Third Party. This Agreement is not intended to and will not be construed to give any Third Party any interest or rights (including any Third Party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby, other than, to the extent provided in ARTICLE XI, the Indemnified Parties.

15.10. Non-exclusive Remedy. Except as expressly provided herein, the rights and remedies provided herein are cumulative and each Party retains all remedies at law or in equity, including the Parties' ability to receive legal damages or equitable relief, with respect to any breach of this Agreement. Neither Party will be required (but, for clarity, will have the right as specified in this Agreement) to terminate this Agreement due to a breach of this Agreement by the other Party.

15.11. Right of Offset; Recoupment. Every liability hereunder of a Party to the other Party is subject to and conditioned upon the recoupment of any and all liabilities owing from the other Party to the first Party, so as to establish a net liability.

15.12. Interpretation. The Article and Section headings used herein are for reference and convenience only, and will not enter into the interpretation of this Agreement. Except as otherwise expressly specified, (a) references to an Article, Section or Exhibit means an Article or Section of, or a Schedule or Exhibit to this Agreement and all subsections thereof, unless another agreement is specified; (b) references in any Section to any clause are references to such clause of such Section; (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto; (d) references to "Laws" mean such Laws as in effect as of the relevant time, including all rules and regulations promulgated thereunder and any successor Laws in effect as of the relevant time, including all then-current amendments thereto; (e) words in the singular or plural form include the plural and singular form, respectively; (f) unless the context requires a different interpretation, the word "or" has the inclusive meaning that is typically associated with the phrase "and/or"; (g) the terms "including," "include(s)," all other conjunctions of the verb "to include," "such as," "e.g." and "for example" mean including the generality of any description preceding such term and will be deemed to be followed by "without limitation"; (h) whenever this Agreement refers to a number of days, such number will refer to calendar days unless Business Days are specified, and if a period of time is specified and dates from a given day or Business Day, or the day or Business Day of an act or event, it is to be calculated exclusive of that day or Business Day; (i) "monthly" means on a calendar month basis, (j) "quarter" or "quarterly" means on a Calendar Quarter basis; (k) "annual" or "annually" means on a Calendar Year basis; (l) "year" means a 365 day period, or 366 day period in the event of a leap year, unless Calendar Year is specified; (m) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement; (n) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa); (o) references to drugs or pharmaceutical products or therapies include biological products or therapies; (p) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement (including any Exhibits or Schedules); (q) neither Party or its Affiliates will be deemed to be acting "on behalf of" the other Party under this Agreement, except to the extent expressly otherwise provided; (r) provisions that require that a Party, or the JSC hereunder

“agree,” “consent” or “approve” or the like will be deemed to require that such agreement, consent or approval be specific and in writing in a written agreement, letter or approved minutes, but, except as expressly provided herein, excluding e-mail and instant messaging; (s) the words “will” and “shall” will be construed to have the same meaning and effect; and (t) conjugates of a defined term shall have the meaning that correlates to the such conjugate as compared to the defined term.

15.13. Further Assurances. Each Party will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be consistent with this Agreement and reasonably necessary to carry out its provisions, including working collaboratively to correct and clerical, typographical, or other similar errors in any document that is to be recorded under this Agreement. Neither Party shall be required under this provision to grant any license or other right not set forth elsewhere in this Agreement.

15.14. Ambiguities: No Presumption. Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties hereto and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption will apply against any Party as being responsible for the wording or drafting of this Agreement or any such provision, and ambiguities, if any, in this Agreement will not be construed against any Party under any rule of construction that requires language to be construed against the Party having authorized the provision, irrespective of which Party may be deemed to have authored the ambiguous provision.

15.15. Export Control. This Agreement is made subject to any restrictions required by applicable Laws concerning the export of products or technical information from the U.S. or other countries which may be imposed upon or related to the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technology licensed to it or other technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, except in compliance with U.S. export Laws and regulations.

15.16. Execution in Counterparts. This Agreement may be executed in counterparts, each of which, when so executed and delivered, will be deemed to be an original, and all of which counterparts, taken together, will constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures delivered by electronic transmission, including in portable document format (.pdf) sent by electronic mail or by any other electronic means (e.g., DocuSign) agreed by the Parties, will have the same effect as physical delivery of the paper document bearing the original signatures, and will be deemed original signatures.

15.17. BioNTech ABC Clause.

(a) OncoC4 agrees that it will not undertake any activities which will result in a violation of any applicable laws, regulations, and applicable industry and professional codes,

including but not limited to applicable local and extraterritorial anti-bribery, anti-corruption and anti-money laundering laws (collectively “PROHIBITED CONDUCT”) in connection with the provision of professional services by OncoC4 to BioNTech for or on BioNTech’s behalf.

(b) In particular, OncoC4 agrees (i) Not to make any offer, payment, or promise to pay money or provide anything of value to a GOVERNMENT OFFICIAL (as defined below) or any other individual and/or legal entity whether directly or indirectly, for the purpose of improperly influencing any act and/or decision of, and/or for securing any improper advantage; (ii) Not to accept, receive, agree to accept and/or receive a payment and/or anything of value from any individual for undue favorable treatment in obtaining, retaining, and/or directing business for, and/or to obtain any undue special concession on behalf of OncoC4 and/or BioNTech; (iii) Not to facilitate any payments to any GOVERNMENT OFFICIAL to expedite a routine government action and/or other official act.

(c) The term “GOVERNMENT OFFICIAL” shall be read broadly and includes (i) individuals acting on behalf of governments on a national, regional and local level (such as elected officials, customs officials, tax officials, etc.); (ii) individuals acting on behalf of government-owned or government-controlled enterprises (such as doctors and staff of public hospitals and universities, etc.); (iii) individuals acting for political parties or as or on behalf of candidates for public office; and (iv) individuals acting on behalf of public international organizations (such as the WHO, World Bank, OECD, etc.).

(d) OncoC4 agrees that if it becomes aware or has reason to suspect that any person or legal entity acting on OncoC4’s and/or BioNTech’s behalf has engaged in any activities which will result in a violation of any applicable laws, such as local and extraterritorial anti-bribery and anti-corruption Laws, regulations, and applicable industry and professional codes related to the Agreement, then the OncoC4 will immediately report such knowledge or suspicion via the following email address: [***]

(e) OncoC4 agrees to provide reasonable cooperation in any investigation that may be conducted by or on behalf of BioNTech related to business in connection with the Agreement. Upon notice of an intended investigation, OncoC4 will provide, in a reasonable time, to BioNTech or to a third party engaged by BioNTech: (a) access to the relevant persons; and/or (b) access to relevant documents and data (e.g., invoices and requests for expense reimbursement, supporting receipts and substantiation, and original entry records for charges and payments).

(f) OncoC4 acknowledges that the obligations under this ABC Clause (Section 15.17) apply to all its Affiliates, employees, Service Providers and subcontractors. OncoC4 will bind subcontractors who act for or on its behalf under the Agreement by respective contractual clauses encompassing all provisions of this ABC Clause.

(g) Notwithstanding anything else in this Agreement or any other right BioNTech may have, a breach of any of the provisions included in this ABC Clause by OncoC4 shall give BioNTech the right to immediately terminate this Agreement for cause.

15.18. Antitrust Filings. Each of BioNTech and OncoC4 agrees to prepare and make appropriate filings under the U.S. Hart-Scott-Rodino Antitrust Improvements Act (“**HSR Act**”)

and other antitrust requirements relating to this Agreement and the transactions contemplated hereby as soon as reasonably practicable, but in any event within [***] Business Days after the Execution Date, at each Party's own cost and expense. The Parties agree to cooperate in the antitrust clearance process (including (i) keeping the other Party informed of any material communication received in connection with such filings and providing a copy to the other Party if such communication is in writing and (ii) permitting the other Party or its counsel to review in advance, and in good faith consider the views of the other Party or its counsel concerning any submission, filing or communication and the documents submitted therewith intended to be given the U.S. Federal Trade Commission ("FTC") or the Antitrust Division of the U.S. Department of Justice ("DOJ")) and to furnish promptly to the FTC, the DOJ and any other agency or authority, any information reasonably requested by them in connection with such filings. Subject to Section 13.1, the rights and obligations of the Parties under this Agreement shall not become effective until the waiting period provided by the HSR Act, or any other timeline required by another relevant agency or authority, shall have terminated or expired without any action by any government agency to challenge the transaction (the date of such termination or expiration shall be the "**Effective Date**" of this Agreement). Notwithstanding any other provision of this Agreement, each of the representations and warranties made by the Parties in ARTICLE X as of the Execution Date and as of the Effective Date, as indicated in ARTICLE X, shall be true and correct in all respects as of the Execution Date and true and correct in all material respects as of the Effective Date. In the event that antitrust clearance from the FTC, DOJ or any other required agency or authority is not obtained within [***] days after the Execution Date, or such other date as the Parties may mutually agree, this Agreement may be terminated by either Party on written notice to the other. In the event a provision of this Agreement needs to be deleted or substantially revised in order to obtain regulatory clearance of this transaction, the Parties will negotiate in good faith in accordance with Section 15.4.

[signature page follows]

IN WITNESS WHEREOF, each Party has caused this License and Collaboration Agreement to be executed by their respective duly authorized officers as of the Execution Date.

BioNTech SE

BioNTech SE

By: /s/ Sean Marett

By: /s/ Jens Holstein

Name: Sean Marett

Name: Jens Holstein

Title: CBO and CCO

Title: CFO

OncoC4, Inc.

By: /s/ Yang Liu

Name: Yang Liu

Title: President and CEO

Schedule 1.5
AI-025 Amino Acid Sequence

[**]

Schedule 1.8
Description of AI-061

[**]

Schedule 1.14

[**]

[**]

Schedule 1.25
CD80/CD86 Compound

[**]

**Schedule 1.64
ONC-392 Backup Molecules**

**Schedule 1.68
Listed Patents**

Schedule 1.75
Expert Valuation Procedure

In the event that the Parties cannot reach consensus regarding the calculation of Net Sales of a Combination Product in a country in accordance with Section 1.75 within the [***] days following BioNTech's request for negotiation, then the matter shall be resolved as set forth below, by a reputable, independent Third Party who is an expert with at least [***] years of experience in pharmaceutical product valuation (the "**Neutral Expert**");

(a) To initiate resolution by a Neutral Expert, either Party shall send the other Party a written notice that it wishes to resolve the dispute by a Neutral Expert. The date of receipt by the other Party of such written notice is the "**Notice Date**."

(b) Within [***] Business Days following the Notice Date, each Party shall notify the other Party in writing of its appointed expert meeting the qualifications for the Neutral Expert stated above (each, a "**Representative Expert**"). The Representative Experts for each Party shall jointly appoint the Neutral Expert within [***] Business Days thereafter.

(c) Within [***] Business Days after the appointment of the Neutral Expert, each Party shall submit to the other Party and the Neutral Expert a written summary regarding its position with respect to the dispute. Contemporaneously with the submission of its written summary regarding its position, each Party shall provide the other Party and the Neutral Expert with copies of all documents it relied upon in its written summary; *provided*, that each Party may redact any portion of such documents which are covered by an applicable privilege or do not relate to the subject matter of this Agreement.

(d) Within [***] Business Days following receipt of the other Party's written summary regarding its position, each Party may submit an opposition statement of no more than five (5) pages in length (excluding exhibits and declarations). Neither Party will be allowed to conduct any discovery. Neither Party may have any communications (either written or oral) with the other Party's Representative Expert or the Neutral Expert other than for the sole purpose of engaging the expert panel or as expressly permitted in this Schedule 1.75; *provided*, that oral presentations and follow-up written submissions may be made to the Neutral Expert at the Neutral Expert's request. The Neutral Expert may consult in writing with the Representative Experts regarding the submissions made by either Party; *provided*, that both Representative Experts are aware of such consultation and provided an opportunity to respond. Evaluating each Party's written submissions, the Neutral Expert shall, within [***] Business Days following receipt of the written opposition statement, select in total, either BioNTech's submission or OncoC4's submission. Such decision shall be final, binding and not appealable.

(e) The Party whose submission is not selected shall be solely responsible for the expenses and fees of the Neutral Expert and the reasonable costs and fees of the other Party's Representative Expert.

(f) The existence of the dispute, any negotiations, submissions, and the rulings shall be deemed to be Confidential Information of both Parties.

Schedule 1.77
ONC-392 Amino Acid Sequence

[***]

Schedule 1.105
Upstream Agreements

[**]

Schedule 2.1(b)
Permitted Subcontractors

[**]

Schedule 2.7
[] License**

[**]

Schedule 3.1(a)
Initial CDP

[**]

Schedule 9.2(a)
Joint Press Release

[***]

Schedule 10.2(i)
Third-Party Agreements

[**]

Schedule 10.2(j)
[] Agreements**

[**]

Schedule 10.2(k)
[] Agreements**

[**]

Schedule 10.2(q)
Government Funding

[**]

Schedule 13.4(d)
Mediation & “Baseball” Arbitration for Reversion Products

If the Parties are unable to mutually agree on and enter into a Reversion Agreement within [***] days following the effective date of termination and either Party refers the matter to be resolved in accordance with this Schedule 13.4(d) or they otherwise mutually agree, the matter will first be referred to the Senior Officers for resolution. The Senior Officers will attempt to resolve the matter in good faith. If the Senior Officers fail to resolve the matter within [***] Business Days after the date on which the matter is referred to the Senior Officers (unless a longer period is agreed to by the Parties), then either Party may, by written notice to the other Party, submit the matter for resolution by mediation as follows:

The matter shall be submitted within [***] Business Days following receipt of such notice for mediation, for non-binding mediation conducted in accordance with the Rules of the American Arbitration Association, and to bear equally the costs of such mediation (including any fees or expenses of the applicable mediator); *provided, however*, that each Party shall bear its own costs in connection with such mediation. The Parties agree to participate in good faith in such mediation for a period of [***] Business Days or such longer period as the Parties may mutually agree following receipt of the notice for mediation (the “**Mediation Period**”).

In connection with such mediation, the Parties shall cooperate with the American Arbitration Association and with one another in selecting a mediator, being a judge or attorney, with ten (10) years’ experience in the development and commercialization of biopharmaceutical products, who is independent of each Party (*i.e.*, not a current or former employee, consultant, officer, or director, or current stockholder, of either Party or their respective Affiliates, and who does not otherwise have any current or previous business relationship with either Party or their respective Affiliates) and in scheduling the mediation proceedings during the applicable Mediation Period.

The Parties further agree that all information, whether oral or written, provided in the course of any such mediation by any of the Parties, their agents, employees, experts, and attorneys, and by the applicable mediator and any employees of the mediation service, is confidential, privileged, and inadmissible for any purpose, including impeachment, in any litigation, arbitration or other proceeding involving the Parties; *provided*, that any information that is otherwise admissible or discoverable shall not be rendered inadmissible or non-discoverable as a result of its use in such mediation.

If the Parties cannot reach resolution for any reason, including, but not limited to, the failure of either Party to agree to enter into mediation or agree to any compromise on the Reversion Agreement proposed by the mediator, on and following the expiration of the Mediation Period, then either Party may, by written notice to the other Party, submit the matter for final resolution by binding “baseball” arbitration as follows:

The Parties will discuss and endeavor in good faith to select and agree upon a mutually acceptable single neutral arbitrator, being a judge or attorney, with at least ten (10) years’ experience in the development and commercialization of biopharmaceutical products, who is independent of each Party (*i.e.*, not a current or former employee, consultant, officer, or director, or current stockholder, of either Party or their respective Affiliates, and who does not otherwise have any current or previous business relationship with either Party or their respective Affiliates), within [***] days following the end of the Mediation Period; *provided*, that if the Parties are unable or fail to agree upon the arbitrator within such [***] day period, the arbitrator shall be appointed by the American Arbitration Association (or any successor entity thereto) within [***] days thereafter. Except as otherwise mutually agreed by the Parties, the arbitration shall be conducted in accordance with the American Arbitration Association’s Final Offer

Arbitration Supplementary Rules, or the equivalent successor rules then in effect to the extent consistent with and modified by this Schedule 13.4(d).

Within [***] Business Days after the selection of the arbitrator (or such other time as the Parties mutually agree), each Party will submit to the arbitrator and the other Party such Party's proposed form of Reversion Agreement and a memorandum in support thereof, not exceeding ten (10) pages in length. Within [***] days after receiving each Party's proposal, the arbitrator will, as final and binding, either (i) select one of the two proposed Reversion Agreements (without modification) provided by the Parties or (ii) introduce a Reversion Agreement containing the terms, conditions, and elements of both of the [***] Reversion Agreement proposed by the Parties; provided, that such proposed Reversion Agreement represents compromise positions between the two Reversion Agreements proposed by the Parties, in each case that the arbitrator believes, in order of priority, is: (i) most closely in accordance with the terms and conditions of the Agreement and the intent of the Parties in entering into the Agreement, (ii) most fair and equitable to both Parties under the circumstances, and (iii) most commercially reasonable. The arbitrator may combine elements of each Parties' proposed Reversion Agreement, so long as the arbitrator's proposed Reversion Agreement does not introduce new positions that are not a compromise between the proposals made by either Party in each Party's proposed Reversion Agreement, or award any other relief or take any other action. Absent fraud or manifest error, the decision of the arbitrator will be final and binding on the Parties, and the Parties shall promptly execute and enter into a Reversion Agreement in the form selected by the arbitrator.

Each Party shall pay its own costs and expenses in connection with the arbitration and shall be responsible for [***] of the fees and expenses of the arbitrator. The Parties agree that the arbitrator's decision may be enforced in any court of competent jurisdiction.

*** Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) the type of information that the Registrant treats as private or confidential.

CONFIDENTIAL

AMENDMENT No. 1
to the License and Collaboration Agreement
between BioNTech SE and OncoC4, Inc.

This Amendment No. 1 to the License and Collaboration Agreement (this “**Amendment**”) is entered into as of February 14, 2024 (“**Amendment No. 1 Effective Date**”) by and between BioNTech SE, a public limited company in the form of a Societas Europaea organized under the laws of the Federal Republic of Germany, with its corporate seat at An der Goldgrube 12 55131 Mainz, registered with the commercial register of the Local Court of Mainz under HRB 48720 (“**BioNTech**”), and OncoC4, Inc., a Delaware corporation having business offices at 9640 Medical Center Drive, Rockville, MD 20850 (“**OncoC4**”). OncoC4 and BioNTech are each referred to herein, individually, as a “**Party**” and, collectively, as the “**Parties**.”

WHEREAS, BioNTech and OncoC4 are parties to that certain License and Collaboration Agreement, dated as of March 17, 2023 and Effective Date as of April 25, 2023 (the “**Agreement**”), concerning the Exploitation of Licensed Products on the terms and subject to the conditions more particularly set forth therein.

WHEREAS, the Agreement provides for the joint Development of Mono/PD-1 Combinations, and for BioNTech to solely Develop Other Combinations.

WHEREAS, it was the original intent of the Parties that the Parties would jointly Develop Licensed Single Products as Mono/PD-1 Combinations, including where a Licensed Single Product is used as part of a combination regimen with (i) one or more PD-1 Product, (ii) one or more SOC Product, or (iii) one or more PD-1 Product and one or more SOC Product.

WHEREAS, the Parties mutually desire to amend, modify and restate certain terms and conditions of the Agreement to clarify the joint Development by the Parties of Mono/PD-1 Combinations.

NOW THEREFORE, in consideration of the premises and the mutual covenants herein contained, it is mutually agreed as follows:

1. DEFINITIONS

Unless otherwise defined herein, capitalized words in this Amendment shall have the meaning attributed to them in the Agreement (including as amended hereby).

2. AMENDMENTS

The Parties agree that, as of the Amendment No. 1 Effective Date, the Agreement is amended as set forth in this Section 2.

2.1 The following definition shall be added to Article 1 in appropriate alphabetical order:

“**Standard of Care Product**” or “**SOC Product**” means, [***]”

- 2.2 Section 1.111 of the Agreement is hereby amended by deleting the reference to the defined term “Mono/PD-1 Combinations” and replacing it, in appropriate alphabetical order, with the reference to the defined term “Mono/PD-1/SOC Combinations”.
- 2.3 The first sentence of Section 3.1(a)(i) of the Agreement is hereby deleted in its entirety and replaced with the following:
- “OncoC4 and BioNTech shall use Commercially Reasonable Efforts to conduct Development activities with respect to the Licensed Compound and Licensed Products, either (A) as a monotherapy, (B) as a Licensed Single Product used as part of a combination regimen with one or more (I) SOC Product or (II) PD-1 Product, or (C) as a Licensed Single Product used as part of a combination regimen with both one or more SOC Product and one or more PD-1 Product ((A)-(C) collectively, the “**Mono/PD-1/SOC Combinations**”), in each case, in accordance with a joint clinical development plan (the “**CDP**”) approved by the JSC in accordance with the terms of this Agreement.”
- 2.4 All references in the Agreement to “Mono/PD-1 Combinations” are hereby deleted in their entirety and replaced with references to “Mono/PD-1/SOC Combinations”.

3. INTEGRATION

Except for the sections of the Agreement specifically amended hereunder, all terms and conditions of the Agreement remain and shall remain in full force and effect. This Amendment shall hereafter be incorporated into and deemed part of the Agreement and any future reference to the Agreement shall include the terms and conditions of this Amendment.

4. APPLICABLE LAW & JURISDICTION

This Amendment shall be governed by, and construed in accordance with, the laws which govern the Agreement, and the Parties submit to the jurisdiction and dispute resolution provisions as set forth in the Agreement.

5. COUNTERPARTS

This Amendment may be executed in counterparts, each of which, when so executed and delivered, will be deemed to be an original, and all of which counterparts, taken together, will constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures delivered by electronic transmission, including in portable document format (.pdf) sent by electronic mail or by any other electronic means (e.g., DocuSign) agreed by the Parties, will have the same effect as physical delivery of the paper document bearing the original signatures, and will be deemed original signatures.

[Remainder of Page Intentionally Left Blank – Signature Page to Follow]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Amendment to be executed by their duly authorized representatives as of the Amendment No. 1 Effective Date.

BioNTech SE

By: /s/ James Ryan

Name: James Ryan

Title: Chief Legal Officer

OncoC4, Inc.

By: /s/ James DeYonker

Name: James DeYonker

Title: SVP, Head of Legal and IP

BioNTech SE

By: /s/ Jens Holstein

Name: Jens Holstein

Title: CFO

*** Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) the type of information that the Registrant treats as private or confidential.

Confidential

LICENSE AND COLLABORATION AGREEMENT

by and between

DUALITY BIOLOGICS (SUZHOU) CO. LTD.

and

BIONTECH SE

dated as of March 16, 2023

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LICENSE AND COLLABORATION AGREEMENT

This License and Collaboration Agreement (the “**Agreement**”) is entered into as of March 16, 2023 (the “**Effective Date**”), by and between **Duality Biologics (Suzhou) Co. Ltd.**, a corporation organized and existing under the laws of the People’s Republic of China (“**Duality**”), having a place of business at Unit 1105-1106, No 868 Ying Hua Road, Pudong New District, Shanghai, China, and **BioNTech SE**, an company organized and existing under the laws of Germany, having a place of business at An der Goldgrube 12, D-55131 Mainz, Germany (“**Licensee**”).

Recitals

Whereas, Duality is a clinical stage company focusing on the discovery and development of the next generation ADC therapeutics to treat patients in cancer and autoimmune diseases;

Whereas, Licensee is engaged in the research, development and commercialization of active immunotherapies for patient-specific approaches to the treatment of diseases;

Whereas, Licensee desires to obtain from Duality, and Duality desires to grant to Licensee, an exclusive sublicensable license under the Duality Licensed IP to Develop, Manufacture and Commercialize the Licensed Products in the Field in the Territory (each as defined below), subject to the terms and conditions of this Agreement; and

Whereas, The Parties desire to collaborate in the Development, Manufacture and Commercialization of the Licensed Products in accordance with the terms and conditions of this Agreement.

Now, Therefore, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Duality and Licensee hereby agree as follows:

Article 1 DEFINITIONS

- 1.1 “**ABC Terms**” shall mean those terms set out in **Schedule 1.1** of this Agreement.
- 1.2 “**Accounting Standards**” shall mean with respect to a Selling Party (as defined below) International Financial Reporting Standards endorsed by the European Union or other applicable standard accounting principles used by Sublicensees.
- 1.3 “**ADC**” shall mean any construct comprising an Antibody(ies) linked to a non-Antibody chemical species with a therapeutic or biological activity or function, including non-Antibody chemical species that (i) directly kills, slows or stops the growth of a tumor cell through such compound’s primary mechanism of action (“**Cytotoxic Payload**”) or (ii) [***].
- 1.4 “**Additional Active(s)**” shall mean any active pharmaceutical or biologic ingredient(s) that is not the Licensed Compound.
- 1.5 “**Affiliate**” shall mean any company or entity controlled by, controlling, or under common control with a Party or another entity. For the purpose of this definition,

an entity shall be deemed to “**control**” another entity, if it owns directly or indirectly, more than fifty percent (50%) of the outstanding voting securities, capital stock, or other comparable equity or ownership interest of such entity, or possession, direct or indirect, of the power to direct or cause the direction of the management or policies of an entity (whether through ownership of securities or other ownership interests, by contract or otherwise).

1.6 “**Alliance Manager**” shall have the meaning provided in Section 3.9.

1.7 “**Annual Net Sales**” shall mean for a particular Licensed Product the total Net Sales for a particular Calendar Year.

1.8 “**Antibody**” shall mean any antibody (including murine, chimeric, human, humanized, recombinant, transgenic, grafted, phage display derived, or single chain antibody), or antigen binding fragment thereof. [***].

1.9 “**Anti-Corruption Laws**” means all applicable anti-bribery and anti-corruption laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, the U.K. Bribery Act 2010 and the PRC Anti-Money Laundering Law and the comparable Applicable Laws of any countries in which candidates or Licensed Products, payments or services will be provided or procured under or pursuant to this Agreement.

1.10 “**Applicable Laws**” shall mean collectively the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, of any Governmental Authority and any license, franchise, permit or similar right granted under any of the foregoing (including Regulatory Approvals) and any policies and other requirements of or from any court, arbitrator, Regulatory Authority or governmental agency or Governmental Authority having jurisdiction over or related to the subject item or subject person, including all applicable GXPs, Anti-Corruption Laws, Applicable Data Protection Laws, accounting and recordkeeping laws, export control laws and laws relating to interactions with health care professionals and government officials.

1.11 “**Applicable Data Protection Law**” shall mean all Applicable Laws in any jurisdiction relating to privacy or the processing or protection of personal data or personal information, including the General Data Protection Regulation (EU) 2016/679 (GDPR), the UK Data Protection Act 2018, the e-Privacy Directive (2002/58/EC) and the comparable in other jurisdictions and all guidance issued by any applicable data protection authority.

1.12 “**Biosimilar Product**” shall mean with respect to a particular Licensed Product in a given country, a product comprising an ADC sold by a Third Party not authorized by Licensee or its Affiliates or Sublicensees that is approved by the applicable Regulatory Authority for such country through an application or submission filed with a Regulatory Authority for marketing approval of a biologic product claimed to be biosimilar or interchangeable to such Licensed Product, including an application filed under 42 U.S.C. § 262(k) (or any successor thereto) or any similar laws or regulations in a country outside the United States in reliance on data generated for a Regulatory Approval of such Licensed Product.

1.13 “**Business Day**” shall mean any day that is not a Saturday, a Sunday or any other day on which banks are required or authorized by law to close in Mainz,

Rhineland-Palatine (in Germany) or any government mandated holiday in Mainland China.

1.14 “Calendar Quarter” shall mean each period of three (3) consecutive months commencing on January 1, April 1, July 1 or October 1 (or any portion thereof at the beginning or end of the Term or other relevant period).

1.15 “Calendar Year” shall mean each period of twelve (12) consecutive months commencing on January 1 and ending on December 31 (or any portion thereof at the beginning or end of the Term or other relevant period).

1.16 “Cell Banks” shall have the meaning provided in Section 6.3.

1.17 “Change of Control” means, with respect to either Party: (a) a merger, acquisition, reorganization, or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, acquisition, reorganization, or consolidation; (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner, directly or indirectly, of more than fifty percent (50%) of the combined voting power of the outstanding securities of such Party; or (c) a transfer to a Third Party of all or substantially all of its assets relating to this Agreement.

1.18 “Clinical Trial” shall mean a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, Registrational Trial or other human clinical trial conducted after the Regulatory Approval of a product in a country, which trial may be conducted to (a) enhance scientific knowledge of such product (e.g., for expansion of product labeling), (b) due to a request or requirement of a Regulatory Authority in such country, (c) is otherwise designed to establish that a product is reasonably safe for continued testing and to identify adverse reactions and ascertain the safety of the product, or (d) investigate the safety and efficacy of the product for its intended use, and to define warnings, precautions and adverse reactions that may be associated with the product in the dosage range to be prescribed.

1.19 “CMC” means chemistry, manufacturing and controls with respect to the Licensed Compound or Licensed Products.

1.20 “CMO” shall mean a Third Party contract manufacturing organization.

1.21 “Collaboration IP” means [***].

1.22 “Combination Product” shall mean a [***].

1.23 “Commercialization” shall mean, with respect to a product, any and all activities undertaken before and after obtaining Regulatory Approvals relating specifically to the pre-launch, launch, promotion, detailing, marketing, pricing, reimbursement, sale, importing, exporting or transporting such product, and distribution of such product, including strategic marketing, sales force detailing, advertising, market product support, all customer support, product distribution, and invoicing and sales activities, but excluding Development and Manufacturing. **“Commercialize”**, **“Commercialized”** and **“Commercializing”** shall have the correlative meanings.

1.24 “**Commercialization Plan**” shall have the meaning provided in Section 7.2.

1.25 “**Commercially Reasonable Efforts**” shall mean, [***].

1.26 “**Committee**” shall have the meaning given in Section 3.3.

1.27 “**Competing Product**” shall mean, [***].

1.28 “**Competitive Change of Control**” shall mean a Change of Control of Duality where the incoming Third Party and/or its Affiliates is a Competitor.

1.29 “**Competitor**” shall mean [***].

1.30 “**Confidential Information**” shall mean all Know-How and other proprietary scientific, technical, clinical, marketing, financial or commercial information or Data Controlled by a Party or its Affiliates, which one Party or any of its Affiliates has furnished or made available to the other Party or its Affiliates, whether in oral, written or electronic form. The existence and terms of this Agreement shall be deemed Confidential Information of each Party.

1.31 “**Control**” (including any variations such as “**Controlled**” and “**Controlling**”) shall mean, with respect to any Know-How, Patents or other intellectual property rights, possession by a Party or Third Party of the right, power and authority (whether by ownership, license or otherwise, other than by virtue of any rights granted under this Agreement) to grant access to, to grant use of, or to grant a license or a sublicense to such Know-How, Patents or intellectual property rights without violating the terms of any agreement or other arrangement with any Third Party. Notwithstanding anything in this Agreement to the contrary, a Party and its Affiliates will be deemed to not Control any Know-How, Patents, or other intellectual property rights that are in-licensed or acquired by such Party or its Affiliates from a Third Party after the Effective Date, unless the other Party agrees to (a) comply with the terms and conditions of the agreement under which such Know-How, Patents, or other intellectual property rights were in-licensed or acquired by such Party; and (b) pay all amounts that such Party would be obligated to pay in connection with the grant, maintenance and exercise of a (sub)license as reasonably allocable to such other Party for use in its territory under such Know-How, Patents, or other intellectual property rights.

1.32 “**Cover**” shall mean, [***].

1.33 “**CRO**” shall mean a contract research organization.

1.34 “**Data**” shall mean all data, including non-clinical data, preclinical data and clinical data, including pharmacological, biological, chemical, toxicological, clinical test, safety, clinical and analytical information, quality control, trial, stability and manufacturing processes and techniques data generated by or on behalf of a Party or its Affiliates or their respective Sublicensees (in case of Licensee) and (sub)licensees (in the case of Duality) pursuant to activities conducted under this Agreement.

1.35 [***]

1.36 “**Development**” shall mean, with respect to a pharmaceutical or biological product, any research activities, all non-clinical and clinical drug development activities and processes, [***], regulatory affairs and other activities, in each case, which are

reasonably necessary to prepare submissions for, and obtain or maintain, Regulatory Approval of such product and interacting with Regulatory Authorities regarding the foregoing, including lifecycle management studies and other activities. “**Develop**”, “**Developed**” and “**Developing**” shall have the correlative meanings.

1.37 “Development Budget” shall have the meaning as set forth in Section 1.39.

1.38 “Development Phase” shall mean the period from the Effective Date to the First Commercial Sale of the first Original ADC Licensed Product during which either Party is conducting any Development activities for an Original ADC Licensed Product or Licensed Compound.

1.39 “Development Plan” shall mean a written plan approved by the JSC, describing [***]. The initial Development Plan, unless otherwise agreed on by the Parties, will be agreed by the Parties latest within [***] of the Effective Date.

1.40 “Divestiture” means [***].

1.41 “Disclosing Party” shall have the meaning provided in Section 10.1.

1.42 “Dispute” shall have the meaning provided in Section 15.2.

1.43 “Duality Background IP” shall have the meaning provided in Section 12.1(a).

1.44 “Duality Costs” shall mean any and all costs and expenses that are reasonably incurred by or on behalf of Duality and its applicable Affiliates after the Effective Date in conducting the Ongoing Trials and/or performing other Development activities as agreed hereunder in the Territory pursuant to this Agreement and/or the Development Plan. [***]

1.45 “Duality CMO” shall mean any CMO engaged by Duality or any Affiliate of Duality.

1.46 “Duality Competing Product” shall mean, [***].

1.47 [***]

1.48 “Duality Indemnitees” shall have the meaning provided in Section 14.1.

1.49 “Duality Know-How” shall mean any and all Know-How (including Data) that (a) is Controlled by Duality or any of its Affiliates as of the Effective Date or at any time during the Term and (b) are necessary or reasonably useful for the Development, Manufacture or Commercialization of or to otherwise exploit the Licensed Compound or Licensed Products in the Field in the Territory, including but not limited with respect to (a) and (b), the Know-How (including Data) contained in Duality Solely Owned Collaboration IP, [***]. Notwithstanding the foregoing, Duality Know-How shall not include (i) any Know-How (including Data) Controlled by any Third Party that becomes an Affiliate of Duality after the Effective Date as a result of a merger, acquisition or other similar transaction, unless such Know-How (including Data) is used by either Party in the Development, Manufacturing or Commercialization of the Licensed Compound or Licensed Products, and (ii) any Know-How that is related to any Additional Active or other proprietary compound or product Controlled by

Duality or any of its Affiliates. A description of Duality Know-How as of the Effective Date is attached hereto on **Schedule 1.49**.

1.50 “**Duality Licensed IP**” shall mean Duality Know-How and Duality Patents.

1.51 “**Duality Linker-Payload**” shall mean [***].

1.52 “[***]” shall mean any new or useful invention, discovery, adaptation, redesign, modification, improvement, enhancement, contribution or other desirable change generated in the course of performing activities under this Agreement that is solely relating to [***].

1.53 [***]

1.54 “**Duality Linker-Payload Patents**” shall mean any and all Duality Patents claiming the Duality Linker-Payload.

1.55 “**Duality Patents**” [***].

1.56 “**Duality Product Patents**” [***].

1.57 “**Duality Solely Owned Collaboration IP**” shall have the meaning provided in Section 12.1(b).

1.58 “**Duality Solely Owned Collaboration Patents**” shall have the meaning provided in Section 12.1(b).

1.59 “**EC Indication**” means endometrial cancer.

1.60 “**Effective Date**” shall have the meaning provided in the introductory paragraph of this Agreement.

1.61 “**Election Notice**” shall have the meaning given in Section 2.8.

1.62 “**EMA**” means shall mean the European Medicines Agency and any successor entity thereto.

1.63 “**EC Expansion Trial**” shall have the meaning set forth in Section 1.133 in the definition of “Phase II Dose Expansion Trial.”

1.64 “**Executive Officers**” shall have the meaning provided in Section 3.5.

1.65 “**FDA**” shall mean the U.S. Food and Drug Administration and any successor entity thereto.

1.66 “**Field**” shall mean all uses.

1.67 “**First Commercial Sale**” shall mean, with respect to an Original ADC Licensed Product, [***].

1.68 “**First Dosing**” shall mean, with respect to a Clinical Trial, or any portion thereof, dosing of the first human subject in such Clinical Trial or such portion thereof.

1.69 “**Force Majeure Event**” shall have the meaning provided in Section 16.10.

1.70 “**FTE**” shall mean full time equivalent.

1.71 “**Fully Burdened Manufacturing Cost**” shall mean, with respect to any Original ADC Licensed Product supplied by or on behalf of Duality: [***].

1.72 “**GCP**” means any and all applicable laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the ethical conduct of Clinical Trials, including without limitation the U.S. Code of Federal Regulations (CFR) Title 21, ICH GCP Guidelines E6(R2) as amended from time to time, national legislation implementing European Community Directive 2001/20/EC (if and as still applicable), European Community Directive 2005/28/EC, and, following the applicable transition periods, the Clinical Trial Regulation (EU) No. 536/2014 (the “CTR”) and the rules, regulations and guidelines applying in the context of the CTR, and the equivalent in other countries or regions.

1.73 “**GCLP**” shall mean any and all applicable laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the treatment of human laboratory samples from Clinical Trials, including the relevant principles from GCP and the EMA’s reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples, as amended from time to time.

1.74 “**Global Trial**” shall mean a Clinical Trial designed to obtain Regulatory Approvals for a Licensed Product in multiple countries through the conduct of a Clinical Trial in multiple countries, regions and/or medical institutions and conducted as part of one (1) unified Clinical Trial or separately but concurrently in accordance with a common Clinical Trial protocol.

1.75 “**GLP**” means any and all applicable laws, rules, regulations, guidelines and generally accepted standards and requirements regarding quality control for laboratories to ensure the consistency and reliability of results, including without limitation the CFR Title 21, national legislation implementing European Community Directives 2004/9/EC and 2004/10/EC as amended, and the OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, and the equivalent in other countries or regions. For the purposes of this Agreement, GLP also includes the principles of Good Clinical Laboratory Practice and applicable guidelines promulgated under the ICH guidelines.

1.76 “**GMP**” means any and all applicable laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the quality control and manufacturing of pharmaceutical products, including without limitation the CFR Title 21, Parts 11, 210, 211, 600 and 610, applicable ICH Guidelines including without limitation Q7 for “Active Pharmaceutical Ingredients”, national legislation implementing European Community Directive 2001/83/EC and Commission Directive 2003/94/EC as amended, EudraLex – Volume 4 of the Rules Governing Medicinal Products in the European Union including annexes, the CTR, Commission Delegated Regulation 2017/1569, the Detailed Commission Guideline (2017) 8179, and the equivalent in other countries or regions.

1.77 “**Governmental Authority**” is to be broadly interpreted and includes any multi-national or public international organization or authority, national, federal, state, local, municipal, provincial, foreign government or other governmental authority of any

nature (including any governmental division, prefecture, branch, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal, or body entitled to exercise any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power, and any Regulatory Authority.

1.78 “**GXP**” shall mean collectively, all relevant and applicable good practice quality guidelines and regulations, encompassing such internationally recognized standards as GMP, GCP, GLP and GCLP, Good Distribution Practice (GDP), Good Pharmacovigilance Practice, Good Pharmacoepidemiology Practice and Good Review Practice.

1.79 “**HER2**” shall mean (a) receptor tyrosine-protein kinase erbB-2, and (b) any naturally occurring variants thereof, in each case including any isoforms, polymorphisms, variants, and truncated forms, and in each case to the extent such variant, isoform, polymorphism, variant and truncated form are produced from an allele of the same gene.

1.80 “**HER2 BC Indications**” means HER2-positive breast cancer (as one Indication) and HER2-low breast cancer (as the other Indication).

1.81 [***]

1.82 “**HER2-Low BC Expansion Trial**” has the meaning set forth in Section 1.133 in the definition of “Phase II Dose Expansion Trial.

1.83 “**HKIAC**” shall have the meaning given in Section 15.2.

1.84 “**ICH**” shall mean the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use.

1.85 [***]

1.86 “**IND**” shall mean an investigational new drug application, clinical study application, Clinical Trial exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

1.87 “**Indemnitee**” shall have the meaning provided in Section 14.3.

1.88 “**Indemnitor**” shall have the meaning provided in Section 14.3.

1.89 “**Indication**” means, [***].

1.90 “**JDC**” shall have the meaning provided in Section 3.2(b).

1.91 “**JIPC**” shall have the meaning provided in Section 3.2(a).

1.92 “[***]” shall have the meaning provided in Section 12.1(d).

1.93 “[***]” shall have the meaning provided in Section 12.1(d).

1.94 “**JSC**” shall mean the joint steering committee to be established by the Parties pursuant to Section 3.1.

1.95 “Know-How” shall mean any and all technical, scientific, regulatory and other information, trade secrets, results, knowledge, techniques, materials (including cell lines) and data, in whatever form and whether or not confidential, proprietary, whether or not patentable, invention disclosures, plans, inventions, assays, designs, protocols, and formulas, processes, practices, methods, knowledge, know how, skill, experience, ideas, concepts, test data (including pharmacological, toxicological and clinical test data), analytical and quality control data, formulae, specifications, marketing, pricing, distribution, cost, sales, and manufacturing data or descriptions. “Know-How” includes any rights including copyright, database or design rights protecting such Know-How. For clarity, Know-How does not include issued Patents or published patent application or the inventions claimed thereby.

1.96 “License Payments” shall have the meaning provided in Section 9.3(b).

1.97 “Licensed Compound” shall mean the ADC developed by or on behalf of Duality and known as DB-1303 comprising trastuzumab. The structure of the Licensed Compound is delivered to Licensee by Duality on or before the Effective Date.

1.98 “Licensed Product” shall mean (i) Original ADC Licensed Product, (ii) [***], or (iii) [***]. Unless otherwise set forth herein, the term “Licensed Product” shall also include a Combination Product.

1.99 “Licensee Added Trials” shall have the meaning given in Section 4.4.

1.100 “Licensee Competing Product” shall mean, [***].

1.101 [***]

1.102 “Licensee Indemnitees” shall have the meaning provided in Section 14.2.

1.103 “Licensee Know-How” shall mean any and all Know-How that is Controlled by Licensee or any of its Affiliates and that is comprised by the Licensee Solely Owned Collaboration IP. Notwithstanding the foregoing, Licensee Know-How shall not include (i) any Know-How Controlled by any Third Party that becomes an Affiliate of Licensee after the Effective Date as a result of a merger, acquisition or other similar transaction, unless such Know-How is used by Licensee in the Development, Manufacture or Commercialization of the Licensed Compound or Original ADC Licensed Products, and (ii) any Know-How that is related to any Additional Active or other proprietary compound or product Controlled by Licensee.

1.104 “Licensee Licensed IP” shall mean the Licensee Know-How and Licensee Patents.

1.105 [***]

1.106 “Licensee Patents” shall mean any and all Patents that are Controlled by Licensee or any of its Affiliates and that are comprised by the Licensee Solely Owned Collaboration Patents. Notwithstanding the foregoing, Licensee Patents shall not include (i) any Patent Controlled by any Third Party that becomes an Affiliate of Licensee after the Effective Date as a result of a merger, acquisition or other similar transaction, and (ii) any Patent that Covers any Additional Active or other proprietary compound or product Controlled by Licensee provided that such Patent does not Cover the Licensed Compound or Original ADC Licensed Product.

1.107 “**Licensee Solely Owned Collaboration IP**” shall have the meaning provided in Section 12.1(b).

1.108 “**Licensee Solely Owned Collaboration Patents**” shall have the meaning provided in Section 12.1(b).

1.109 “**Losses**” shall have the meaning provided in Section 14.1.

1.110 “**MAA**” shall mean an application to a Regulatory Authority for the authorization to place a product on the market in the applicable country, region or a regulatory jurisdiction, including New Drug Application and Biologics License Application, and shall include all amendments and supplements thereto, filed with the applicable Regulatory Authority to gain approval to place such product on the market in the applicable jurisdiction.

1.111 “**MAH**” means the holder of the Marketing Authorization.

1.112 “**Mainland China**” means the mainland of the People’s Republic of China.

1.113 “**Major European Market**” means [***] for the purpose of this Agreement.

1.114 “**Manufacture**” shall mean, with respect to a Licensed Product, activities related to the manufacture and supply of such Licensed Product, including manufacturing supplies for Development or Commercialization, packaging, labeling, in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance and quality control activities related to manufacturing and release of product, ongoing stability tests, storage, and shipment and regulatory activities directly related to any of the foregoing, but not including any Development or Commercialization activities. “**Manufactured**” and “**Manufacturing**” shall have the correlative meanings.

1.115 “**Manufacturing IP**” means any Patents and Know-How that are (i) generated, developed or conceived during the course of performing activities under this Agreement depending on Duality Licensed IP, and (ii) specifically related to, and (iii) necessary for the Manufacture of the Duality Linker-Payload; notwithstanding the foregoing, Manufacturing IP shall exclude Licensee Background IP.

1.116 “**Marketing Authorization**” shall mean the authorization by all relevant Regulatory Authorities of an MAA in a given country or regulatory region/jurisdiction and the granting of the required authorization for the sale of a product (but which will not include any Pricing and Reimbursement Approvals unless required by Applicable Law of the respective country to initiate marketing and selling of a product in such particular country).

1.117 “**MCB**” shall mean the master cell bank.

1.118 “**Medical Affairs Activities**” shall mean, with respect to the Territory, the coordination of medical information requests and field based medical scientific liaisons with respect to an Original ADC Licensed Product, including activities of medical scientific liaisons, activities involving key opinion leaders, and the provision of medical information services with respect to an Original ADC Licensed Product.

1.119 “Multi-Specific ADC Product” shall mean [***].

1.120 “Negotiation Period” shall have the meaning set forth in Section 2.8.

1.121 “Net Sales” shall mean, [***]

1.122 “New Indication” shall mean an entirely separate and distinct disease or medical condition in humans for which the Original ADC Licensed Product is authorized.

1.123 “Non-Arbitral Subject Matter” shall have the meaning given in Section 15.4.

1.124 “Offer Notice” shall have the meaning given in Section 2.8.

1.125 “Ongoing Trials” means the Clinical Trials currently being conducted by Duality in the Territory and the Retained Territory entitled *A Phase 1/2a, Multicenter, Open-Label, Non-Randomized First in Human Study to Assess the Safety, Tolerability, Pharmacokinetics, and Preliminary Antitumor Activity of DB-1303 in Patients With Advanced/Metastatic Solid Tumors with NCT number NCT05150691*. For clarity, the Ongoing Trials include both a Phase I Clinical Trial phase, and the Phase II Dose Expansion Trials.

1.126 “Option Package Delivery Date” shall have the meaning provided in Section 11.2.

1.127 “Original ADC Licensed Product” shall mean [***].

1.128 “Party” shall mean Licensee or Duality individually, and **“Parties”** shall mean Licensee and Duality collectively.

1.129 “Patents” shall mean (a) patent applications filed in the applicable jurisdiction; (b) all patents, including supplemental protection certificates, that have issued or in the future issue from any of the foregoing, including utility models, design patents and certificates of invention; and (c) all divisionals, continuations, continuations-in-part, reissues, re-examination certificates, renewals, extensions or additions to any such patents and patent applications (as applicable).

1.130 “Pharmacovigilance Agreement” shall have the meaning provided in Section 5.7.

1.131 “Phase I Clinical Trial” means a human clinical trial of a product, the principal purpose of which explores the optimal dose and is a determination of initial tolerance or safety of such product in healthy volunteers or the target patient population, as described in 21 CFR 312.21(a) (as amended or any replacement thereof), or a similar clinical trial prescribed by the Regulatory Authority in a country other than the United States.

1.132 “Phase II Clinical Trial” means a human clinical trial of a product, the principal purpose of which is a determination of safety and efficacy in the target patient population (i.e. “proof of concept”), as described in 21 C.F.R. 312.21(b) (as amended or any replacement thereof), or a similar clinical trial prescribed by the Regulatory Authority in a country other than the United States.

1.133 “Phase II Dose Expansion Trials” means the Phase II Clinical Trial portion of the Ongoing Trials consisting of two (2) dose expansion cohorts meeting the following criteria: (a) one cohort in HER2-low breast cancer (the “**HER2-Low BC Expansion Trial**”), and (b) one cohort in endometrial cancer (the “**EC Expansion Trial**”).

1.134 “Phase III Clinical Trial” means a human clinical trial of a product, the design of which is acknowledged by the FDA to be sufficient for such clinical trial to satisfy the requirements of 21 C.F.R. 312.21(c) (as amended or any replacement thereof), or a similar human clinical trial prescribed by the Regulatory Authority in a country other than the United States, the design of which is acknowledged by such Regulatory Authority to be sufficient for such clinical trial to satisfy the requirements of a pivotal efficacy and safety clinical trial.

1.135 “Pricing and Reimbursement Approval” shall mean, in any country where a Regulatory Authority authorizes reimbursement for, or approves or determines pricing or level of reimbursement for, pharmaceutical products, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization and/or pricing approval or determination (as the case may be).

1.136 “Product Marks” shall have the meaning provided in Section 7.5.

1.137 “Project Manager” shall have the meaning provided in Section 3.9.

1.138 “Proposed Publication” shall have the meaning provided in Section 10.5.

1.139 “Receiving Party” shall have the meaning provided in Section 10.1.

1.140 “Reduced Royalty Rates” shall mean the reduced royalty rates for the [***] and [***] specified in the second table in Section 8.5.

1.141 “Registrational Trial” shall mean, with respect to a product, a human clinical trial (regardless of whether such clinical trial is referred to as a “Phase II Clinical Trial”, “Phase IIb Clinical Trial”, “Phase II/III Clinical Trial”, “Phase IIb/III Clinical Trial” or “Phase III Clinical Trial”) for such product, the results of which, together with prior information concerning such product, are determined by the sponsor to be intended to be sufficient to establish that such product is safe and effective for its intended Indication to support the filing of an MAA. [***].

1.142 “Regulatory Approval” shall mean any and all approvals, licenses, permits, registrations or authorizations of or from any Regulatory Authority that are necessary to market (including Marketing Authorization) and sell a pharmaceutical product in any country, region or other jurisdiction. For clarity, unless it is required by the Applicable Law to initiate marketing and selling of a product in a particular country, Regulatory Approval shall not include Pricing and Reimbursement Approval.

1.143 “Regulatory Authority” shall mean with respect to a country, any national, federal, supranational, state or local regulatory agency, council, department, bureau or other governmental or regulatory authority having the administrative authority to regulate the development or marketing of pharmaceutical products in any country, region or jurisdiction, including the Regulatory Approvals.

1.144 [*]**

1.145 “Regulatory Materials” shall mean, with respect to a product, regulatory applications (including MAA) and all applications, filings, submissions, notifications, materials, communications, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority in order to Develop, Manufacture, market, sell or otherwise Commercialize such product in a particular country, region or jurisdiction.

1.146 “Remedial Action” shall have the meaning provided in Section 5.8.

1.147 “Retained Territory” shall mean Mainland China, Hong Kong Special Administrative Region and Macau Special Administrative Region.

1.148 “Review Period” shall have the meaning provided in Section 10.5.

1.149 “[*]”** shall have the meaning provided in Section 2.8.

1.150 “Royalty Term” shall have the meaning provided in Section 8.6.

1.151 “Rules” shall have the meaning provided in Section 15.2.

1.152 “SEC” shall have the meaning provided in Section 10.4(a)(i).

1.153 “Separate” means, [***].

1.154 “Solely Owned Collaboration IP” shall mean Duality Solely Owned Collaboration IP and Licensee Solely Owned Collaboration IP, as applicable.

1.155 “Solely Owned Collaboration Patents” shall mean Duality Solely Owned Collaboration Patents and Licensee Solely Owned Collaboration Patents, as applicable.

1.156 “Sublicense” shall mean a license, sublicense, covenant not to sue or other rights granted by Licensee to a Third Party under the rights it receives from Duality in accordance with Section 2.2, to Develop, Manufacture or Commercialize a Licensed Compound or a Licensed Product, but excluding any grant of rights to or agreement with (a) any Third Party acting as a service provider or subcontractor for such Party or its Affiliates, or (b) any Third Party wholesaler, distributor, or the like.

1.157 “Sublicensee” means a Third Party that is receiving rights under a Sublicense.

1.158 “Successful Completion” shall mean, [***].

1.159 “Target” shall mean, with regard to an Antibody or ADC and a biological target in question, that such Antibody or ADC demonstrates meaningful binding activity to such biological target and **“Targeting”** shall be construed accordingly.

1.160 “Tax Withholdings” shall have the meaning provided in Section 9.3(b).

1.161 “[*] Dosing”** shall mean, with respect to a Clinical Trial, or any portion thereof, dosing of the [***] in such Clinical Trial or such portion thereof.

1.162 “Term” shall have the meaning provided in Section 13.1.

1.163 “**Territory**” shall mean worldwide except Retained Territory. For clarity, Territory shall include Taiwan.

1.164 “**Third Party**” shall mean any entity other than Licensee and its Affiliates and Duality and its Affiliates.

1.165 “**Third Party Claims**” shall have the meaning provided in Section 14.1.

1.166 “**UNCITRAL**” shall have the meaning given in Section 15.2.

1.167 “**United States**” or “**U.S.**” shall mean the United States of America, including its territories and possessions as recognized by the United Nations from time to time, but in all cases including, for clarity, Puerto Rico

1.168 “**US\$**” or “**U.S. Dollars**” shall mean U.S. dollars, the lawful currency of the U.S.

1.169 “**Upfront Payment**” shall have the meaning provided in Section 8.1.

1.170 “**Valid Claim**” shall mean [***].

1.171 “**Wind-Down or Transfer Plan**” shall mean a plan for the wind-down or transfer of any ongoing Development, Manufacture and Commercialization (if any) activities of Licensee with respect to the Licensed Products for which the license grant in Section 2.1 has been terminated and the transfer of relevant Licensed Products, as applicable.

1.172 “**WCB**” shall mean the working cell bank.

Article 2 LICENSE

2.1 License Grant.

(a) **Territory License Grant.** Subject to the terms and conditions of this Agreement (including Duality’s retained rights in Section 2.4), Duality hereby grants to Licensee, during the Term, an exclusive (even as to Duality and its Affiliates), royalty-bearing license, with the right to sublicense through multiple tiers (in accordance with Section 2.2), under Duality Licensed IP to Develop, have Developed, Manufacture, have Manufactured, use, sell, offer for sale, import and otherwise Commercialize or have Commercialized or exploit the Licensed Products in the Field in the Territory.

(b) **Retained Territory License Grant.** Subject to the terms and conditions of this Agreement (including Duality’s retained rights in Section 2.4), Duality hereby grants to Licensee a sole license to Develop, have Developed, Manufacture or have Manufactured the Licensed Compound and the Licensed Products in the Retained Territory solely for the purpose of Developing, Manufacturing and Commercializing the Licensed Products in the Field in the Territory. For clarity and without limiting any rights granted to the Licensee hereunder, Duality has the full rights to Develop, Manufacture and have

Manufactured, Commercialize and otherwise exploit the Licensed Compound and Original ADC Licensed Products in the Retained Territory.

2.2 Sublicense Rights.

(a) **Right to Sublicense.** Subject to the terms and conditions of this Agreement, Licensee and its Affiliates shall have the right to grant Sublicenses (through multiple tiers) under Duality Licensed IP, to (i) any Affiliate, or (ii) to any Third Party.

(b) **Sublicense Terms.** [***].

(c) **Licensee's Responsibility.** Licensee shall use Commercially Reasonable Efforts to ensure that the performance by any of its Affiliates, Sublicensees and subcontractors hereunder is in accordance with the applicable terms of this Agreement. With respect to a patent challenge by the Sublicensee against any Duality Patents, if Licensee fails to cause such Sublicensee to cease such violation within a reasonable period of time, Licensee shall, in so far as it is not prohibited under the Applicable Laws, terminate the sublicense agreement.

2.3 Negative Covenants. In so far as it is not prohibited under the Applicable Laws, Licensee hereby covenants on a country-by-country basis not to, and not to permit or cause any Affiliate to [***]. Notwithstanding the foregoing, this Section shall in no way restrict [***], its Affiliates, its Sublicensees or their CMOs and other authorized Third Party under this Agreement from undertaking any research, Development, Manufacturing, Commercialization, or other exploitation or engaging in any activities involving [***] that anyone not subject to this Agreement may legally undertake before the Effective Date and during the Term in the Territory and elsewhere, [***]. [***]

2.4 No Implied Licenses; Retained Rights. No right or license under any Patents or Know-How of either Party is granted or shall be granted by implication. All such rights or licenses are or shall be granted only as expressly provided in the terms of this Agreement. Duality hereby expressly reserves all rights not expressly licensed to Licensee in Section 2.1, including (i) all rights under the Duality Licensed IP with respect to the Licensed Compound and Original ADC Licensed Products in the Retained Territory, subject to Licensee's co-exclusive license as set forth in Section 2.1(b), (ii) all rights under the Duality Licensed IP to exercise its rights or perform its obligations under this Agreement, and (iii) all rights under the Duality Licensed IP to conduct Development activities in the Territory for the sole purpose of Developing or Commercializing the Original ADC Licensed Products in the Field in the Retained Territory, *provided that* any such Development activities in the Territory in relation to the Original ADC Licensed Product and Licensed Compound shall be undertaken for Duality by Licensee or its Affiliates, or Sublicensees or designated subcontractors.

2.5 License to Duality. Licensee hereby grants to Duality a non-exclusive, non-transferrable, non-sublicensable (unless a sublicense was consented by Licensee in writing and is in compliance with the license terms set out in Section 2.2(b) which would apply *mutatis mutandis*), royalty-free license under the Licensee Licensed IP, during the Term of this Agreement solely to (i) perform, either itself, through its Affiliates, or through subcontractors, its obligations under this Agreement, including its Manufacturing and supply obligations under Sections 6.1, 6.4 and 6.5, and (ii) limited to the Field and the Retained Territory, to Develop, Manufacture or have Manufactured (or solely for exporting to the Territory, only where requested by Licensee to supply the

Original ADC Licensed Product), or Commercialize the Licensed Compound or Original ADC Licensed Products. Duality shall use Commercially Reasonable Efforts to ensure that the performance by any of its Affiliates or subcontractors hereunder is in accordance with the applicable terms of this Agreement. With respect to a patent challenge by a (sub)licensee against any Licensee Patents, if Duality fails to cause such (sub)licensee to cease such violation within a reasonable period of time, Duality shall, in so far as it is not prohibited under the Applicable Laws, terminate such (sub)license agreement. Duality shall be responsible for any actions of its Affiliates and subcontractors who act on behalf of Duality to perform activities assigned to Duality (for or on behalf of Licensee) pursuant to this Agreement, to the same extent as if such actions had been taken by Duality itself, and Licensee shall have the right to proceed directly against Duality without any obligation to first proceed against such Affiliate, sublicensee and subcontractor.

2.6 Know-How Transfer. Within [***] days of the Effective Date, Duality shall at its cost and expense provide to Licensee [***] the documents embodying all Duality Know-How (including CMC documentation to the extent available to Duality or any of its Affiliates as of the Effective Date) Controlled by Duality or any of its Affiliates as of the Effective Date, including but not limited to the structure of the Licensed Compound (to the extent not transferred to Licensee prior to the Effective Date, [***]). A description of such documents for the initial Know-How Transfer is attached as **Schedule 2.6** hereto. Duality shall promptly (and in any event no later than [***] from the existence of such Know-How) inform Licensee of the existence of any additional Duality Know-How that becomes Controlled by Duality after the Effective Date and during the Term. The Parties shall discuss the timing and means of the transfer of additional Duality Know-How and Duality shall provide electronic copies of such additional Duality Know-How to Licensee in accordance with Licensee's request, in a manner in line with that for the initial Know-How transfer and at no additional cost to Licensee.

2.7 Non-Competition.

[***]

2.8 [*]**

**Article 3
GOVERNANCE**

3.1 Joint Steering Committee. Within [***] days following the Effective Date, the Parties shall establish a JSC comprised of an equal number of representatives from each Party to approve, plan, coordinate, integrate monitor and oversee the Parties' activities in the Territory in relation to the Development of the Original ADC Licensed Product and facilitate information exchange between the Parties under this Agreement. The JSC, as may be conducted through the applicable Subcommittee, shall in particular:

(a) review, discuss and coordinate the overall strategy for the Development of the Original ADC Licensed Products in the Territory;

(b) review, discuss and approve any proposed amendments or revisions to the Development Plan(s) of the Original ADC Licensed Product, including all related budgets of the Development activities;

(c) review, discuss and approve any study protocols relating to the Development Plan(s) (and any amendments thereto) of the Original ADC Licensed Products;

(d) review, discuss and serve as a forum for the sharing of information between the Parties regarding the operation of any Development activities of the Original ADC Licensed Product in the Territory and in the Retained Territory;

(e) oversee and coordinate the on-going disclosure, sharing and/or transfer of Collaboration IPs generated in or related to the Development of the Original ADC Licensed Products in the Territory;

(f) review and discuss any matters relating to the Regulatory Approvals and Regulatory Materials to be submitted to any Regulatory Authority in the Territory in respect of the Original ADC Licensed Product;

(g) coordinate supply of Original ADC Licensed Product in accordance with Article 6;

(h) review and discuss the clinical protocol of and Duality's potential participation in any Global Trial (including the HER2-Low BC Phase III Global Trial) sponsored by Licensee or any of its Affiliates and Sublicensees or Licensee Added Trials; and

(i) perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or as determined by the Parties in writing.

3.2 Subcommittees. From time to time during the Term, the JSC may establish and disband one or more subcommittee(s) (each, a "**Subcommittee**") to oversee particular activities of the Parties, and the JSC may assign to such subcommittee(s) duties or tasks independent of the duties of the JSC, or delegate part of such duties of the JSC to such subcommittee(s) as it deems necessary and appropriate.

(a) **Joint IP Committee.** Without limiting the generality of the foregoing subsection (a), no later than [***] days after the Effective Date (unless otherwise agreed by the Parties) the JSC shall establish an intellectual property committee (the "**Joint IP Committee**" or "**JIPC**") led by Licensee and comprised of an equal number of representatives from each Party. The JIPC shall provide a forum for discussion of the patenting strategies of the Original ADC Licensed Products and coordinate the Parties' efforts in accordance with the provisions set forth in Article 12 and other matters related to the prosecution and maintenance of intellectual property rights hereunder, including submissions to and addressing notices from Regulatory Authorities that relate to regulatory-patent linkage procedures and proceedings. The JSC shall determine the desired membership of the JIPC and once formed, Licensee's committee members shall determine the time, place and procedure of meetings. [***]

(b) **Joint Development Committee.** Without limiting the generality of the foregoing subsection (a), no later than [***] days after the Effective Date, the JSC shall establish a joint development committee (the "**Joint Development Committee**" or "**JDC**") led by Licensee and comprised of an equal number of representatives from each Party. The JDC shall (i) oversee the implementation and progress of the Development Plan in the Territory, (ii) discuss and propose

to the JSC for approval any amendments to the Development Plan, (iii) oversee any Global Trials.

3.3 Composition; Meetings. The JSC and each Subcommittee (each, a “Committee”) shall be composed of [***] representatives from each Party (or such other equal number of representatives of each of Licensee and Duality as the JSC may determine), and each Party shall notify the other Party of its initial JSC representatives within [***] days after the Effective Date. Each Party shall designate a representative to be the co-chairperson of the JSC and Licensee shall designate a representative to chair each Subcommittee led by it, in each case who shall schedule meetings, prepare meeting agendas and meeting minutes and follow up on action items. Each Party may request and convene a Committee meeting and propose agenda therefor at any time. With respect to the JSC, these responsibilities will alternate between the Parties or each co-chairperson, as applicable, with Licensee’s co-chairperson taking the responsibility for the first meeting of the JSC. Each Party may change its representatives to the JSC (or any Subcommittee) from time to time in its sole discretion, effective upon notice to the other Party of such change. Each Party’s representatives in each Committee shall possess appropriate experience with respect to the issues falling within the functions of such Committee and requisite seniority within such Party’s organization, and shall have the authority to make decisions on behalf of the Party they represent.

3.4 Non-Member Attendance. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend a meeting of any Committee (in a non-voting capacity) in the event that the planned agenda for such Committee meeting would require such participants’ expertise; provided that if either Party intends to have any Third Party (including any consultant or counsel) attend such a meeting, such Party shall provide prior written notice to the other Party, shall obtain approval from such other Party for such Third Party to attend (which shall not be unreasonably withheld by the notified Party), and shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

3.5 Decision-Making. The representatives of each Party will have, collectively, [***] at each Committee on all matters brought before such Committee. The Committees may not take any action or decide any matter except at a meeting attended by [***] representing each Party and with unanimous consent.

(a) **JSC Decisions.** Except where consent or approval on any matter by a Party is expressly required herein, if after reasonable discussion and good faith consideration of each Party’s view on any matter within the decision-making authority of the JSC (including those matters referred to the JSC by any Subcommittee), the representatives of the Parties on the JSC cannot reach an agreement as to such matter within [***] Days after such matter was brought to the JSC for resolution or after such matter has been referred to the JSC, such disagreement shall be referred to [***] (collectively, the “Executive Officers”) for resolution. If the Executive Officers cannot resolve such matter within [***] days (or such other timeframe as the JSC may request in consideration of the urgency of such referred matter) after such matter has been referred to them, then:

- (i) [***] shall be entitled to make final decisions with respect to:
[***]
- (ii) [***] shall be entitled to make final decisions on the [***]:

[***]; and

(iii) with respect to [***]:

and (A) [***] shall have final decision-making authority with respect to matters relating to [***];

(B) [***] will have final decision-making authority with respect to matters relating to [***].

(b) **JIPC Decisions.** Except where consent or approval on any matter by a Party is expressly required herein, if after reasonable discussion and good faith consideration of each Party's view on any matter within the decision-making authority of the JIPC, together with the assistance of each Party's outside intellectual property counsel (as required and pursuant to Section 3.4), the representatives of the Parties on the JIPC cannot reach an agreement as to such matter within [***] Days after such matter was brought to the JIPC for resolution or after such matter has been referred to the JIPC, such matter shall be escalated to the JSC by either Party.

(c) **JDC Decisions.** Except where consent or approval on any matter by a Party is expressly required herein, if after reasonable discussion and good faith consideration of each Party's view on any matter within the decision-making authority of the JDC, the representatives of the Parties on the JDC cannot reach an agreement as to such matter within [***] Days after such matter was brought to the JDC for resolution or after such matter has been referred to the JDC, such disagreement shall be escalated to the JSC by either Party.

(d) **Deadlock Resolution.** In case of a deadlock with respect to the decision-making process of the JSC, Article 15 shall apply.

3.6 Limitations on Authority. The JSC shall have only such powers as are expressly assigned to it in this Agreement, and such powers shall be subject to the terms and conditions of this Agreement. Without limiting the generality of the foregoing, the JSC shall not have the power to amend this Agreement, and no decision of the JSC may be in contravention of any terms and conditions of this Agreement. For clarity, the JSC shall have no decision-making authority regarding any Development, Manufacturing, Commercialization or other activity in the Retained Territory save as contemplated by Section 3.5(a) or otherwise expressly provided in this Agreement.

3.7 Meetings. The JSC will hold a meeting every [***] months until the Development Phase ends, and afterwards every [***] months, or as otherwise determined by the JSC. Such meetings may be in person, via videoconference, or via teleconference. The location of in-person meetings will be determined by the Parties. At least [***] Days prior to each JSC meeting, each Party shall provide written notice to the other Party of agenda items proposed by such Party for discussion at such meeting, together with appropriate information related thereto. Reasonably detailed written minutes will be kept for all JSC meetings. Meeting minutes will be prepared [***] and sent to each member of the JSC for review and approval within [***] Days after the meeting. Minutes will be deemed approved unless a member of the JSC objects to the accuracy of such minutes within [***] Days of receipt. In the event of any such objection that is not resolved by mutual agreement of the Parties, such minutes will be amended to reflect such unresolved dispute.

3.8 Discontinuation of JSC. The JSC shall continue to exist until the Parties mutually agree to disband the JSC. Once the JSC is disbanded, the JSC shall have no further obligations under this Agreement and, thereafter, the Alliance Managers shall be the points of contact for the exchange of information under this Agreement, and the Parties shall reach decision directly on matters that are subject to the decision of the JSC as set forth in Section 3.1.

3.9 Project and Alliance Managers. Each Party shall appoint an individual, who is an employee of such Party, to act as a project manager (the “**Project Manager**”) who shall be responsible for implementing and coordinating activities and facilitating the exchange of information between the Parties. Each Party shall appoint an individual, who is an employee of such Party, to act as its alliance manager under this Agreement within [***] Days after the Effective Date (the “**Alliance Manager**”). [***] The Project Managers shall: (a) serve as the primary points of contact between the Parties for the purpose of providing the other Party with information on the progress of a Party’s activities under this Agreement; (b) be responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties. The Alliance Managers shall: (a) serve as the primary points of contact between the Parties for any issues arising under this Agreement; (b) facilitate the prompt resolution of any disputes; and (c) attend JSC and Subcommittee meetings (in each case, as a non-voting participant); provided that the Alliance Managers shall not count toward the number of representatives that each Party may have on each such Committee. An Alliance Manager may also bring any matter to the attention of the JSC, if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party may replace its Project Manager or Alliance Manager at any time upon written notice to the other Party.

Article 4 DEVELOPMENT

4.1 Overview; Diligence.

(a) Except as expressly provided herein with respect to the Ongoing Trials, Licensee Added Trials (as applicable) and the preparatory activities for the HER2-Low BC Phase III Global Trial as set forth in Section 4.6(b), Licensee (itself and through its Affiliates and their respective Sublicensees) shall be responsible, at its own expense, for the Development of the Original ADC Licensed Products in the Field in the Territory under the oversight of JSC. Without limiting the generality of the foregoing, Licensee shall, subject to the Development Plan (i) use Commercially Reasonable Efforts to Develop and seek Regulatory Approval for [***] in the Field in each of [***], and (ii) use Commercially Reasonable Efforts to perform the Development activities assigned to it under the Development Plan(s) and in compliance with Applicable Laws (including GCP); and (iii) use Commercially Reasonable Efforts to dose the first patient in a Registrational Trial within [***] months for the applicable HER2-low breast cancer Indication or EC Indication after Successful Completion of each of the HER2-Low BC Expansion Trial and EC Expansion Trial conducted by or on behalf of Duality, taking into account the timelines and interactions with Regulatory Authorities. Licensee’s (including its Affiliates’ and Sublicensees’, as applicable) failure to dose the first patient in a Registrational Trial within such [***] months period shall not be a breach of this provision if the delay is caused by any safety issues, a requirement or decision from a

Regulatory Authority, Force Majeure Events, or any other events that are outside the reasonable control of Licensee, its Affiliates or Sublicensees. If such a delay happens, Licensee shall promptly notify Duality (within [***] Days) and shall provide detailed explanations for such delay. The Parties shall engage in good faith discussions and the Licensee shall consider in good faith and reasonably address Duality's input and comments with respect thereto.

(b) Without limiting the foregoing, Licensee shall use Commercially Reasonable Efforts to (i) make all regulatory submissions to the applicable Regulatory Authorities within the Territory in respect of the Original ADC Licensed Product; and (ii) obtain Regulatory Approval for Original ADC Licensed Products in the Territory, in each case of (i) and (ii) in accordance with the Development Plan.

(c) Without limiting Sections 4.3 and 4.4, where responsibility for conducting any Development activities (falling within the scope of this Agreement) is designated by Licensee to Duality or its Affiliates and subcontractors, Duality, its Affiliates and subcontractors shall perform the Development activities assigned to it under the Development Plan(s), in compliance with Applicable Laws (including GCP).

4.2 Development Plan. The Parties will agree on the initial Development Plan, which sets forth the scope, timeline and responsibilities of each Party of the Development activities to be conducted by or on behalf of Licensee in order to obtain Regulatory Approvals for the Original ADC Licensed Products in the Territory. From time to time during the Term, either Party may propose written amendments and updates to the then-current Development Plan, and shall submit such amendments and updates to the JSC for review and approval. The amendment of the Development Plan shall become effective only upon the approval of JSC.

4.3 Ongoing Trials. As of the Effective Date, the Parties have agreed that Duality will continue to be the sponsor of the Ongoing Trials in the Territory so that the Ongoing Trials can be continued without interruption. Subject to Licensee's obligations to fund and reimburse Duality Costs incurred in the Territory in accordance with Section 8.2 (save, for the avoidance of doubt, with respect to the portion of the Ongoing Trials that is conducted in the Retained Territory which shall be the sole responsibility of Duality), Duality shall comply with all Applicable Laws when conducting the activities set out in the Development Plan and use Commercially Reasonable Efforts to conduct the activities set out in the Development Plan including to (a) continue to conduct the Phase I Clinical Trial phase of the Ongoing Trial, and (b) initiate and conduct the Phase II Dose Expansion Trials in the U.S., Australia and Mainland China in accordance with the Development Plan (including the timeline specified therein) and complete the First Dosing in 2023, unless Duality's failure to comply with such timeline is caused by any safety issues, a requirement or decision of a Regulatory Authority, Force Majeure Events that are outside the reasonable control of Duality, its Affiliates or (sub)licensees. If such a delay happens, Duality shall promptly notify Licensee (within [***] Days) and shall provide detailed explanations for such delay. The Parties shall engage in good faith discussions and Duality shall consider in good faith and reasonably address Licensee's input and comments with respect thereto.

4.4 Licensee Added Trials. [***]

4.5 Global Trials. [***]

4.6 Phase [*] Clinical Trial.**

[***]

4.7 Development Records. Each Party shall maintain or cause to be maintained complete, current and accurate records of all activities conducted by or on behalf of it pursuant to the Development Plan(s), and all Know-How and other information resulting from such activities. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes. Each Party shall, and shall ensure that its Affiliates and their Sublicensees will, document all non-clinical studies and Clinical Trials in formal written study records in accordance with all Applicable Laws, including applicable national and international guidelines such as ICH, GCP, GCLP and GLP. To the extent permitted by the Applicable Laws, each Party shall have the right to review and copy such records of the other Party at reasonable times and to obtain access to review the original to the extent necessary or useful for regulatory, patent or other reasonable purposes for the purpose of fulfilling its obligations under this Agreement upon reasonable notice to such other Party and at a time and location mutually acceptable to the Parties.

4.8 Development Reports. Each Party shall keep the other Party reasonably and timely informed of the progress and results of its and its Affiliates', subcontractors' and Sublicensees'/(sub)licensees' work under the Development Plan(s) (including prompt reporting of available pre-clinical and clinical data). Without limiting the generality of the foregoing, each Party shall provide the other Party with a written report no later than [***] days after the end of each Calendar Year setting forth in details the Development activities performed during such Calendar Year and the results thereof, and comparing such activities with the Development Plan(s) for such time period. Such reports prepared by each Party shall be provided at a level of detail reasonably sufficient to enable the other Party to determine compliance with its obligations under this Agreement. At each JSC meeting, the Parties shall discuss the status, progress and results of the Development activities conducted by the Parties pursuant to this Agreement. Each Party shall promptly respond to the other Party's reasonable questions or requests for additional information relating to such Development activities. In the event that Duality is engaged by Licensee to conduct Development activities in the Territory, Duality shall send the Development report on [***] basis, setting forth the Development activities performed [***].

Article 5 REGULATORY

5.1 Overview of Conduct of Regulatory Activities.

(a) Licensee (itself and through its Affiliates and Sublicensees, as applicable) shall be responsible for all of the costs for all regulatory activities with respect to the Licensed Products in the Territory after the Effective Date. [***], Licensee (or its Affiliate or Sublicensees) shall be the sponsor and holder of all Regulatory Approvals for the Licensed Products in the Territory. For clarity, Licensee (or one of its Affiliates or their Sublicensees) shall always be the MAH of the Original ADC Licensed Products in the Territory.

(b) Following the Effective Date, Duality shall provide Licensee with one (1) electronic copy of the Regulatory Materials related to the Licensed Compound or Original ADC Licensed Products in the Territory existing and possessed by Duality as of the Effective Date. At any time during the Term, if Duality is the sponsor or holder of the Regulatory Materials and upon Licensees' request in writing, Duality shall provide Licensee with electronic copies of the Regulatory Materials related to the Licensed Compound or Original ADC Licensed Products in the Territory received and possessed by Duality after the Effective Date promptly and no later than [***] Days after such Regulatory Materials become available.

5.2 Regulatory Filing; Ownership.

(a) **Regulatory Filings.** Except with respect to regulatory filings related to the Ongoing Trials and the Licensee Added Trials (if any), for which Duality shall be responsible or the Parties agree otherwise, (i) Licensee (and its Affiliates, or Sublicensees as applicable) shall lead and have sole control over preparing and submitting all regulatory filings related to the Licensed Compound and Original ADC Licensed Products, including all applications for Regulatory Approval, in the Territory at Licensee's sole cost and expense, and (ii) Duality shall be responsible for the preparation and submission of any regulatory filings in the Retained Territory at Duality's sole cost and expense. With respect to regulatory filings for the Ongoing Trials or and the Licensee Added Trials (if any) that are prepared by Duality, Duality shall submit all such regulatory filings to the JSC for its review and approval.

(b) **Ownership.** Other than any Regulatory Approvals or applications therefor that are related to the Ongoing Trials in the Territory or Licensee Added Trials for which Duality is the sponsor, Licensee (or its Affiliates, or Sublicensees as applicable) shall own any and all Regulatory Approvals (and applications for Regulatory Approvals), and any other regulatory filings related to the Licensed Compound and Licensed Products in the Territory, including Data and data in the regulatory filings and Regulatory Materials, which shall be held in the name of Licensee or its designees.

(c) **English Translation.** To the extent that the original language is not English, Duality shall provide Licensee with a certified full English translation of all Regulatory Materials.

5.3 Interactions with Regulatory Authorities. Insofar as it relates to the Ongoing Trials in the Territory and Licensee Added Trials (if any) where Duality is the sponsor, Duality shall lead interactions with Regulatory Authorities in the Territory; provided that JSC shall have final decision making authority in relation to such interactions with Regulatory Authorities and Duality shall follow all instructions provided to it by the JSC in this regard and shall provide Licensee with (i) access to or copies of all material written or electronic communication received by Duality or its Affiliates from any Regulatory Authorities in the Territory and in the Retained Territory (if applicable), and (ii) copies of all meeting minutes with any Regulatory Authorities in the Territory and in the Retained Territory (if applicable). In addition, Duality shall provide Licensee with written notice of any scheduled material meeting, conference, or discussion with a Regulatory Authority related to Regulatory Approvals related to the Ongoing Trials. Licensee (or its designee) shall have the right to (i) attend and participate in all such meetings with Regulatory Authorities related to the Ongoing Trials, and all telephone conferences and preparation meetings of Duality or its

Affiliates related to any such meeting, (ii) provide input on the regulatory filings in the Territory and in the Retained Territory (to the extent this impacts the position of Licensee in the Territory), and (iii) have final decision making authority in relation to any unsettled matter between the Parties with respect to regulatory filings in the Territory. Subject to the foregoing, Licensee (and/or its Affiliates, or Sublicensees as applicable) shall have the sole right to conduct all communications with Regulatory Authorities, including all meetings, conferences and discussions (including advisory committee meetings), with regard to the Licensed Compound and Licensed Products in the Territory, including in respect of the Licensee Added Trials where Licensee (or its Affiliates or Sublicensees, as applicable) is the sponsor (if any). Without limited the forgoing, the Parties agree that they will collaborate with each other as necessary to ensure the successful progression of interactions with Regulatory Authorities with respect to all trials relating to the Licensed Compound and Original ADC Licensed Products in the Territory and in the Retained Territory (to the extent this impacts the position of Licensee in the Territory).

5.4 [***]. [***], Duality shall transfer and assign, or shall cause the transfer or assignment, to Licensee or its designee (at Duality's cost and expense for Ongoing Trials and at Licensee's cost and expense for Licensee Added Trials), Duality's, or any of its Affiliates', entire right, title, and interest in and to all IND and other Regulatory Approvals in the Territory, if any, and transfer all Regulatory Materials with respect to the Licensed Compound and Original ADC Licensed Products in the Territory that are owned, controlled or possessed by Duality or any of its Affiliates, unless the Parties agree otherwise.

5.5 Replacement. Licensee may decide to replace Duality to be the sponsor of any Clinical Trials in the Territory at any time after the Effective Date of the Agreement. Once Licensee informs Duality of its decision to replace Duality as the sponsor of the Ongoing Trial or a Licensee Added Trial in writing, Duality shall transfer a copy of all Regulatory Materials in its original language; to the extent that the original language is not English, Duality shall provide a certified full English translation of all documents to Licensee. If the replacement was caused by a breach of the applicable terms of this Agreement, Applicable Laws or the GXP by Duality, the costs and expenses reasonably incurred by Licensee in relation or as a result of such replacement shall be borne by Duality.

5.6 Data Access; Right of Reference; Access to Regulatory Materials.

[***]

5.7 Pharmacovigilance. Within [***] days of Effective Date, the Parties shall enter into a pharmacovigilance agreement regarding the Licensed Compound and Original ADC Licensed Products (the "**Pharmacovigilance Agreement**"), which shall set forth standard operating procedures governing the collection, investigation, reporting, and exchange of safety information sufficient to permit each Party to comply with its regulatory and other legal obligations within the applicable timeframes. In the event of any inconsistency between the terms of this Agreement and the Pharmacovigilance Agreement, the terms of this Agreement shall prevail and govern, except to the extent such conflicting terms relate directly to the pharmacovigilance responsibilities of the Parties (including the exchange of safety data), in which case the terms of the Pharmacovigilance Agreement shall prevail and govern. Prior to the Parties entering into the Pharmacovigilance Agreement, Duality is and shall continue to be the owner of the global safety database for the Original ADC Licensed Products. The Pharmacovigilance Agreement can be amended at Licensee's request during the Term

and as a preparation to the Commercialization, at least [***] months' ahead of the first MAA submission. At any time during the Term, upon reasonable prior notice, during regular business hours and under obligations of confidentiality, Licensee (or its designees) shall be entitled to audit (i) any of Duality's, its Affiliates', or any of their respective CRO or CMOs' manufacturing sites; and (ii) any of Duality's or its Affiliates' clinical sites, as selected by Licensee in its sole discretion, to assess Duality's compliance with all GXP's and all matters arising under the Pharmacovigilance Agreement, in each case of the foregoing (i) and (ii), only in respect of any Clinical Trials run by Duality for Licensee in the Territory; provided that such audit shall not be conducted more than once in any given Calendar Year, unless it is a for-cause audit. If (a) such audit by Licensee identifies any material non-compliance by Duality (via its subcontractors) or its Affiliates (via its subcontractors) of the GXP's or the Pharmacovigilance Agreement in the Territory, and (b) such material non-compliance is confirmed to be an uncured material breach on the part of Duality pursuant to Section 13.3, then the provisions of Section 13.8 shall apply.

5.8 Remedial Actions. Each Party shall notify the other immediately, and promptly confirm such notice in writing, if it obtains information indicating that any Original ADC Licensed Product may be subject to any recall, corrective action, patent regulatory procedures or other regulatory action in the Territory or the Retained Territory by any Governmental Authority or Regulatory Authority (a "**Remedial Action**"). The Parties shall assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. The Parties shall collaborate in good faith and endeavor to reach an agreement on Remedial Action related decisions save that where there is any unsettled issues in relation to any Remedial Action related matters (i) with respect to the Territory, Licensee shall have the final decision making authority and Duality shall take all actions reasonably requested by Licensee in relation to such Remedial Action, save that where such Remedial Action is reasonably likely to impact Duality's position in respect of the Original ADC Licensed Product or any Regulatory Authorities in the Retained Territory, no action will be taken by Licensee (unless immediate action is required to comply with Applicable Laws and mitigate further damage arising from the Remedial Action) without Duality's prior written consent, and (ii) with respect to the Retained Territory, Duality shall have the final decision making authority and Licensee shall take all actions reasonably requested by Duality in relation to such Remedial Action, save that where such Remedial Action is reasonably likely to impact Licensee's position in respect of the Original ADC Licensed Product or any Regulatory Authorities in the Territory, no action will be taken by Duality without Licensee's prior written consent. The cost and expenses of any Remedial Action shall be borne by the Party whose action or inaction caused the Remedial Action of the Original ADC Licensed Product.

Article 6 MANUFACTURE & SUPPLY

6.1 Costs of CMC Activities. Duality will conduct CMC activities for the Original ADC Licensed Products according to the scope as agreed upon by the Parties in the Development Plan. [***]

6.2 Transfer of CMC Materials from Duality to Licensee. Following the Effective Date (and thereafter from time to time during the Term upon Licensee's reasonable advance request and to the extent not previously provided), Duality shall provide to Licensee (or its designee) the CMC-related technical documents and CMC-

related technology (and any associated manufacturing process technology) that are necessary or reasonably useful for the Manufacture of the Licensed Compound and Original ADC Licensed Product and are Controlled by Duality or any of its Affiliates as of the Effective Date and which become Controlled by Duality or any of its Affiliates during the Term, and customs and technology export licenses required by Applicable Law for such transfer(s), if any. Within [***] of Licensee's request, Duality or a Duality CMO shall provide Licensee with reasonable assistance and on-site support in respect of the CMC-related technology and associated manufacturing process technology transferred to Licensee pursuant to this Section 6.2. Any assistance required in excess of [***] will be at the Licensee's cost and expense. To the extent that the original language of the CMC Materials (including Third Party agreements) is not English, Duality shall provide a certified full English translation of these materials. The conclusion of new Third Party agreements regarding the CMC activities contemplated under Section 6.1 or the amendment of existing Third Party agreements regarding the same shall be subject to Licensee's prior written approval.

6.3 Transfer of Cell Banks. The Parties will enter into a separate quality agreement and thereafter a supply agreement to manage the logistics and shipping of the transfer of the MCB and WCB (collectively, "Cell Banks") used for the Manufacturing of the Antibody incorporated into the Licensed Products within [***] days after the Effective Date. [***]

6.4 Initial Clinical Supply. Duality shall, by itself or through one or more Duality CMO(s) in the Retained Territory, supply to Licensee, its Affiliates or Sublicensees, [***] and in accordance with a separate clinical supply agreement as contemplated below; provided that Licensee shall be [***]. Unless otherwise agreed by the Parties, the Parties shall negotiate in good faith a clinical supply agreement and related quality agreement with such negotiation to be commenced within [***] days after the Effective Date and completed no later than [***] days after the Effective Date, which clinical supply agreement shall contain customary language regarding supply of the Original ADC Licensed Products to Licensee (including equitable allocation in the event of disruption to or shortage of product supply). [***]

6.5 Ongoing Supply. Except as may otherwise be provided under the clinical supply agreement entered into by the Parties pursuant to Section 6.4 and until the Licensee has qualified a new manufacturing site to Manufacture the Licensed Compound and the Original ADC Licensed Products in the Territory, Licensee shall be solely responsible for (i) Manufacturing the Licensed Compound and Original ADC Licensed Products intended for use in the Territory and (ii) the associated costs and expenses of such Manufacturing activities, subject to Duality's performance of its obligations under this Agreement. Once the Original ADC Licensed Product is approved, [***].

Article 7 COMMERCIALIZATION MATTERS

7.1 Overview; Diligence. Subject to the terms and conditions of this Agreement (including the diligence obligations set forth below), Licensee (itself or through its Affiliates or Sublicensees, as applicable) shall be solely responsible for Commercialization of the Original ADC Licensed Products in the Field in the Territory including: (i) developing and executing a commercial launch and pre-launch plan, (ii) developing the global pricing strategy and negotiating with applicable Governmental

Authorities regarding price and reimbursement of the Original ADC Licensed Products; (iii) marketing, advertising and promotion; (iv) booking sales; (v) distribution and handling all aspects of order processing, invoicing and collection, inventory and receivables; (vi) providing customer support, and performing other related functions; (vii) conforming its practices and procedures to Applicable Laws relating to the marketing, detailing and promotion of the Original ADC Licensed Products in the Field; and (viii) developing and implementing the global and local Medical Affairs Activities and medical information infrastructure required in the Field in the Territory. Licensee shall bear all of the costs and expenses incurred in connection with such Commercialization activities in the Territory. [***]

7.2 Commercialization Plan. No later than [***] months before the anticipated date of the submission of the first MAA for an Original ADC Licensed Product in the Territory, Licensee shall prepare a written Commercialization plan that sets forth the timeline and details of all major Commercialization activities planned for such Original ADC Licensed Product in the Territory (the “**Commercialization Plan**”). The Commercialization Plan shall be updated at least once a year.

7.3 Coordination of Commercialization Activities. The Parties recognize that they may benefit from the coordination of certain activities in support of the Commercialization of an Original ADC Licensed Product across their territories. As such, the Parties may coordinate such activities where appropriate, including scientific and medical communication and Licensed Product positioning. For clarity, Licensee shall not conduct any Commercialization of any Original ADC Licensed Product outside the Territory without Duality’s express prior written consent and Duality shall not conduct any Commercialization of Original ADC Licensed Products outside of the Retained Territory without Licensee’s express prior written consent.

7.4 Commercialization Reports. Licensee shall keep Duality informed of its, its Affiliates’ and Sublicensees’ Commercialization activities in the Territory with respect to each Original ADC Licensed Product and Duality shall keep Licensee informed of Duality’s, its Affiliates’ and sublicensees’ Commercialization activities in the Retained Territory with respect to each Original ADC Licensed Product. In addition, each Party shall make available to the other Party such additional information about its Commercialization activities as may be reasonably requested by the other Party from time to time. Without limiting the generality of the foregoing, Licensee shall, [***], provide Duality with [***].

7.5 Trademarks. Licensee shall be responsible for the registration, filing, maintenance and enforcement of any trademarks (including domain names) developed for the Original ADC Licensed Products in the Field in the Territory (the “**Product Marks**”). The Parties will discuss in good faith and enter into a separate branding agreement outlining terms for ownership, use, management and enforcement of trademarks (including domain names) adopted to identify the Original ADC Licensed Products in the Field in the Retained Territory.

7.6 Original ADC Licensed Products Tracking in the Territory and Retained Territory. Licensee shall, and shall ensure that its Affiliates and Sublicensees, maintain adequate records to permit the Parties to trace the distribution, sale, and use of all Original ADC Licensed Products through all relevant channels (e.g. wholesalers, hospitals and pharmacies) in the Territory. Duality shall, and shall ensure that its Affiliates and (sub)licensees, maintain adequate records to permit the Parties to trace the distribution, sale, and use of all Original ADC Licensed Products through all relevant channels (e.g. wholesalers, hospitals and pharmacies) in the Retained Territory.

7.7 No Diversion. Each Party hereby covenants and agrees that during the Term, and except as expressly permitted by this Agreement, it shall not (and shall cause its Affiliates and Sublicensees (with respect to Licensee), (sub)licensees (with respect to Duality) and subcontractors not to), either itself or through a Third Party, develop, use, market, promote, import, export, sell or actively offer for sale (online or otherwise) the Licensed Products in the other Party's territory. Without limiting the generality of the foregoing, except as mutually agreed by the Parties, each Party shall not (a) engage in any advertising activities relating to the Licensed Products directed primarily to customers in the other Party's territory, or (b) actively or intentionally solicit orders from any prospective purchaser located in the other Party's territory or prospective purchasers whose delivery address is located in the other Party's territory. To the extent permitted by Applicable Laws, including applicable antitrust laws, if a Party receives any order for Licensed Products from a prospective purchaser located in or with a nominated delivery address in a country or jurisdiction in the other Party's territory, such Party shall immediately refer that order to the other Party and shall not accept any such order or deliver or tender (or cause to be delivered or tendered) the Licensed Products under such order. If a Party should reasonably know that a customer or distributor is actively engaged itself or through a Third Party in the sale or distribution of the Licensed Products in the other Party's territory, then such Party shall (i) within [***] Days of gaining knowledge of such activities, notify the other Party regarding such activities and provide all information available to such Party that the other Party may reasonably request concerning such activities and (ii) use Commercially Reasonable Efforts (including cessation of sales or delivery to such customer) necessary to limit such sale or distribution in the other Party's territory, unless otherwise agreed in writing by the Parties prior to such sale or delivery.

Article 8 FINANCIAL TERMS

8.1 Upfront Payment. In partial consideration of Duality's granting of the licenses and rights to Licensee hereunder, Licensee shall make a one-time, non-refundable, non-creditable payment to Duality of [***] (the "**Upfront Payment**") within [***] days after the receipt of an invoice issued by Duality to the Licensee on or after the Effective Date.

8.2 [***]

(a) **Funding Payments.** Licensee shall, within [***] days after the receipt of an invoice issued by Duality to the Licensee on or after the Effective Date, pay to Duality (i) an amount of [***] to fund Duality Costs in connection with the HER2-Low BC Expansion Trial in the Territory; and (ii) an amount of [***] to fund Duality Costs in connection with the EC Expansion Trial in the Territory. Duality's invoice shall include documentation regarding the occurrence of the [***] Dosing in each of the HER2-Low BC Expansion Trial and EC Expansion Trial and supporting documents specifying the expenses spent. Duality will use the amount paid by Licensee solely for administration and conduct of the corresponding Phase II Dose Expansion Trial after the Effective Date (i.e., the HER2-Low BC Expansion Trial or the EC Expansion Trial, as applicable).

(b) [***]

[***]

(c) **Invoicing.** With respect to each of the HER2-Low BC Expansion Trial and the EC Expansion Trial, Duality will issue the first invoice for reimbursement of Duality Costs after Duality's full consumption of the funding as specified in Section 8.2(a) above, and be accompanied with supporting documentation itemizing the breakdown of the costs and expenses that were incurred and are reimbursable hereunder. Thereafter, no later than [***] setting forth the amount of actual Duality Costs incurred during such Calendar Quarter in the Territory which shall be reimbursed by Licensee pursuant to this Section 8.2, along with supporting documentation itemizing the breakdown of the costs and expenses that were incurred and are reimbursable hereunder. With respect to [***], Duality will issue the first invoice for reimbursement of Duality Costs within [***] Days after the first Calendar Quarter after the Effective Date and thereafter the preceding sentence shall apply *mutatis mutandis*. Each invoice issued by Duality shall list Duality Costs actually incurred in U.S. Dollars (and if any item was originally in another currency, the exchange rate used for converting the original currency to U.S. Dollar in accordance with Section 9.2). [***]

(d) **Other Clinical Trials.** At Licensee's request, Duality shall perform any other Clinical Trial (in addition to the Ongoing Trials) of an Original ADC Licensed Product for an Indication other than the HER2 BC Indications and EC Indication. The Parties shall discuss (through the JSC) Licensee's [***].

8.3 Development and Regulatory Milestone Payments of the Original ADC Licensed Product. With respect to the milestone events set forth in the tables below, promptly following the first achievement, whether by Duality or any of Duality's Affiliates (when designated by Licensee) or by Licensee or any of Licensee's Affiliates or Sublicensees, of the corresponding milestone event by the first Original ADC Licensed Product, Licensee or Duality, as the case may be, shall notify the other Party within [***] Days of such achievement, and Licensee shall pay to Duality the corresponding non-refundable, non-creditable milestone payment -within [***] days after the receipt of an invoice issued by Duality to Licensee on or after the achievement of the applicable milestone event:

[***]

[***]

[***]

[***]

8.4 Sales Milestone Payments of the Original ADC Licensed Products. Licensee shall pay to Duality the additional one-time, non-refundable, non-creditable payments set forth in the table below within [***] days after the receipt of an invoice issued by Duality to Licensee on or after the first achievement of each milestone event described below. [***]

[***]

Within [***] days after the end of the Calendar Quarter in which any milestone event set forth above in this Section 8.4 for which a milestone payment is payable is achieved, Licensee shall deliver a written notice to Duality of such achievement, and Licensee shall pay to Duality the corresponding milestone payment within [***] days after the receipt of an invoice issued by Duality to Licensee. For clarity, each of the milestone payments set forth above in this Section 8.4 shall be additive such that if multiple milestone events specified above are achieved in the same Calendar Quarter, then the milestone payments for all such milestone events shall be payable by Licensee.

8.5 Royalties. Licensee shall pay tiered royalties to Duality on Annual Net Sales of: (i) all Original ADC Licensed Products in the Territory in each Calendar Quarter as set forth below, in the first table in this Section 8.5, calculated by [***]; and (ii) any [***] or [***] at the Reduced Royalty Rates for each respective Annual Net Sales threshold, as set forth in the second or third table, as the case may be, in this Section 8.5, calculated by [***].

[***]

[***]

[***]

8.6 Royalty Term. Royalties under Section 8.5 shall be payable, on a [***] basis, during the period beginning on [***] and continuing until the latest of: [***] (the “**Royalty Term**”).

8.7 Royalty Payment Reduction of Licensed Products

[***]

**Article 9
PAYMENT; RECORDS; AUDITS**

9.1 Payment; Reports. Royalties shall be calculated and reported for each Calendar Quarter within [***] days after the end of each Calendar Quarter. Each payment shall be accompanied by a report of [***]. Except as may otherwise be expressly provided herein, Licensee shall not have the right to set off, withhold or make any deduction from any payment of royalties or other payments due to Duality hereunder for any reason whatsoever.

9.2 Exchange Rate; Manner and Place of Payment. All payments hereunder shall be payable in U.S. dollars within [***] days after receipt of an invoice from Duality. With respect to sales of Licensed Products invoiced in a currency other than U.S. dollars, sales milestones and royalties shall be converted into U.S. dollar using the exchange rate mechanism generally applied by Licensee or its Affiliates or Sublicensees for consolidation purposes, in accordance with the Accounting Standards, for the Calendar Quarter for which a payment is due. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Duality, unless otherwise specified in writing by Duality.

9.3 Taxes.

(a) **Taxes on Income.** Except as otherwise provided in this Section 9.3, Licensee shall be solely responsible for the payment of all value added taxes, fees, duties, surcharges, and other deductions or withholding taxes imposed by or on any entity in the Territory in connection with the payments and activities contemplated hereunder. Except as otherwise set forth in this Section, each Party shall be solely responsible for the payment of all taxes imposed on such Party's income arising directly or indirectly from the activities of the Parties under this Agreement.

(b) **Tax Withholdings.** In the event that any withholding tax, fee, duty or surcharge applicable to or assessable in respect of any of the Upfront Payment, development, regulatory or sales milestone payments, or royalty payments to be made by Licensee to Duality under this Agreement (collectively, the "**License Payments**") is required to be withheld and deducted under Applicable Laws ("**Tax Withholdings**"), Licensee (or its Affiliate paying on behalf of Licensee) shall make such deduction and withholding and will pay the remaining License Payments to Duality. For clarity, Licensee's reimbursement of Duality Costs shall not be deemed to be License Payments or subject to any Tax Withholdings.

(c) **Tax Cooperation.** Licensee shall make such deduction of taxes and withholding tax payments to the applicable taxing authority(ies) in a timely manner and shall promptly provide Duality with the appropriate proof of payment and relevant receipt(s) with respect to such deduction or withholding. To the extent permitted by Applicable Laws, Licensee shall provide Duality reasonable assistance in order to allow Duality to obtain the benefit of any present or future treaty against double taxation or refund or reduction in taxes which may apply to the License Payments. Each Party agrees to use commercially reasonable efforts to cooperate with the other Party in claiming refunds, reductions, or exemptions from such deductions or withholdings under any relevant agreement or treaty that is in effect. Duality will provide Licensee with any tax forms or other documentation reasonably necessary in order for Licensee not to withhold or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. If the taxes originally paid or otherwise borne by a Party are in whole or in part subsequently determined not to have been chargeable, all reasonably necessary steps will be taken by each Party to obtain a refund of these undue taxes from the applicable Governmental Authority or other fiscal authority and any amount of undue taxes repaid by such authority to the receiving Party will be transferred to the paying Party within [***] days of receipt.

9.4 Blocked Currency. In the event that, by reason of Applicable Law in any country or region, it becomes impossible or illegal, after reasonable efforts by Licensee to do so, for Licensee or its Affiliate to transfer, or have transferred on its behalf, payments owed Duality hereunder, Licensee shall promptly notify Duality of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country or region to the credit of Duality in a recognized banking institution designated by Duality provided such arrangements are legal under all Applicable Laws.

9.5 Records; Audits. Licensee shall keep, and require its Affiliates and Sublicensees to keep, complete, fair and true books of accounts and records for the purpose of determining the amounts payable to Duality pursuant to this Agreement. Such books and records shall be kept for at least [***] Years following the end of the

Calendar Year to which they pertain. Duality shall have the right to cause an independent, certified public accountant reasonably acceptable to Licensee to audit such records to confirm Net Sales, royalties and other payments for a period covering not more than the preceding [***] Years; provided that (a) such audit shall not be more frequent than once in any [***] month period, and (b) once such accountant has conducted a review and audit of any records pursuant to this Section 9.5 in respect of any given period, it may not subsequently re-inspect such records with respect to such period, unless, in each case of (a) and (b), for cause. Prior to engagement by an independent, certified public accountant, such accountant must have executed and delivered to Licensee and its Affiliates a confidentiality agreement as reasonably requested by Licensee, which will include provisions limiting such accountant's disclosure to Duality to only the results and basis for such results of such inspection. Such audits may be exercised during normal business hours upon reasonable prior written notice to Licensee. Prompt adjustments shall be made by the Parties to reflect the results of such audit. Duality shall bear the full cost of such audit unless such audit discloses an underpayment by Licensee of more than [***] of the amount of royalties or other payments due under this Agreement for any applicable Calendar Quarter, in which case, Licensee shall bear the cost of such audit and shall promptly remit to Duality the amount of any underpayment. Any overpayment by Licensee revealed by an audit shall be fully-creditable against future payment owed by Licensee to Duality (and if no further payments are due, shall be refunded by Duality at the request of Licensee). Any underpayment by Licensee identified by an audit shall not be subject to Section 9.6.

9.6 Late Payments. In the event that Licensee fails to make any payment due under this Agreement (save as set out in Section 9.5), simple interest shall thereafter accrue on the sum due from the due date until the date of payment at [***].

Article 10 CONFIDENTIALITY

10.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party (in such capacity, the "**Receiving Party**") agrees that, during the Term and for [***] years thereafter, it shall keep confidential and shall not publish or otherwise disclose to any Third Party, and shall not use for any purpose other than as expressly provided for in this Agreement or any other written agreement between the Parties, any Confidential Information, including any Know-How, furnished or made available to it by or on behalf of the other Party (in such capacity, the "**Disclosing Party**"). The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to ensure that its, and its Affiliates', employees, agents, contractors, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information. The Receiving Party shall promptly notify the Disclosing Party upon discovery of any unauthorized use or disclosure of the Disclosing Party's Confidential Information.

10.2 Exceptions. Confidential Information shall not include any information which the Receiving Party can prove by competent evidence: (a) is at the time of disclosure, or thereafter becomes, through no act or failure to act on the part of the

Receiving Party, generally known or available to the public or part of the public domain; (b) is known by the Receiving Party and/or any of its Affiliates at the time of receiving such information, as evidenced by its records; (c) is hereafter furnished to the Receiving Party and/or any of its Affiliates by a Third Party, as a matter of right and without restriction on disclosure; or (d) is independently discovered or developed by the Receiving Party and/or any of its Affiliates, without the use of or reference to Confidential Information of the Disclosing Party.

10.3 Authorized Disclosure. Notwithstanding the provisions of Section 10.1, the Receiving Party may disclose Confidential Information of the Disclosing Party as expressly permitted by this Agreement, or if and to the extent such disclosure is reasonably necessary in the following instances:

- (a) filing or prosecuting or defending Patents as permitted by this Agreement;
- (b) disclosure required in connection with any judicial, regulatory or administrative process relating to or arising from this Agreement (including any enforcement hereof) or to comply with applicable court orders;
- (c) disclosure to Affiliates, employees, contractors, consultants or agents of the Receiving Party who have a need to know such information in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement; provided, in each case, that any such Affiliate, actual or potential licensee or Sublicensee, employee, contractor, consultant or agent agrees to be bound by terms of confidentiality and non-use comparable in scope to those set forth in this Article 10;
- (d) such disclosure is made to such Party's attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the Receiving Party, on the condition that such attorneys, independent accountants and financial advisors are bound by confidentiality and non-use obligations consistent with the confidentiality provisions of this Agreement as they apply to the Receiving Party (provided, however, that in the case of financial advisers, including investment bankers, the term of confidentiality may be shortened to [***] years from the date of disclosure and in the case of attorneys, no written agreement shall be required);
- (e) disclosure to existing investors, acquirors or collaborators or potential bona fide investors, acquirors, licensees, Sublicensees or collaborators in connection with due diligence or similar investigations by such Third Parties; provided, in each case, that any such existing or potential investor, acquiror, licensees, Sublicensees or collaborator agrees to be bound by confidentiality and non-use obligations consistent with those contained in this Agreement as they apply to the Receiving Party (but of duration customary in confidentiality agreements entered into for similar purpose);
- (f) disclosure to Regulatory Authorities as required by Applicable Laws in relation to Regulatory Approvals and regulatory procedures, proceedings and other filings;
- (g) disclosure to: (i) Governmental Authorities to the extent useful or necessary to make regulatory filings and obtain or maintain Regulatory

Approvals (including fulfilling post-approval regulatory obligations) for any Licensed Product; (ii) Governmental Authorities, technical committees or similar public health or scientific bodies for purposes of securing product use recommendations, tenders, direct procurement contracts or responding to relevant requests for information; (iii) comply with Applicable Laws with respect to performance under this Agreement; and (iv) to Governmental Authorities in order to respond to inquiries, requests or investigations relating to Licensed Products or this Agreement; and

(h) to the extent mutually agreed to by the Parties in writing.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 10.3(a) or Section 10.3(b), it will, except where impracticable for necessary disclosures, give reasonable advance notice to the other Party of such disclosure requirement and will use its reasonable efforts to secure and cooperate with the other Party, as necessary, to seek and obtain, confidential treatment of such Confidential Information required to be disclosed to the extent legally permissible and will limit the disclosure of that Confidential Information required to be disclosure to (i) to advisors (including lawyers and accountants) or Governmental Authorities on a need to know basis, in each case under appropriate confidentiality provisions or professional standards of confidentiality substantially equivalent to those of this Agreement, or (ii) to the extent agreed to by the Parties.

10.4 Public Announcements.

(a) Press Releases and Publicity.

(i) As soon as practicable following the Effective Date and on a date mutually agreed by the Parties, the Parties shall issue a joint press release announcing the execution of this Agreement in substantially the form attached hereto as **Schedule 10.4**. Except as required by applicable securities laws (including disclosure requirements of the U.S. Securities and Exchange Commission ("SEC") or any stock exchange on which securities issued by a Party or its Affiliates are traded), neither Party shall make any other public announcement or statement, whether oral or written, concerning this Agreement or the subject matter hereof without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed; provided that each Party may make any public statement in response to questions by the press, analysts, investors or those attending industry conferences or financial analyst calls, or issue press releases, so long as any such public statement or press release is not inconsistent with prior public disclosures or public statements approved by the other Party pursuant to this Section 10.4 and which do not reveal non-public information about the other Party. In the event of a required public announcement, to the extent practicable under the circumstances, the Party making such announcement shall provide the other Party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other Party a reasonable opportunity to review and comment upon the proposed text. Licensee shall have final decision making authority in respect of the proposed text of any required public announcement relating to the Licensed Product in the Territory and Retained Territory.

(ii) In the event of termination of this Agreement for any reason, if in the reasonable opinion of the either Party's legal counsel, public disclosure of such termination is required under the Applicable Law or the rules of a stock exchange on which the securities of either Party (or any controlling Affiliate of such Party) are listed

(or to which an application for listing has been submitted), the Parties shall cooperate in good faith to coordinate public disclosure, if any, of such termination and the reasons therefor. The principles to be observed in such disclosures shall be accuracy, compliance with Applicable Law, the rules of the applicable stock exchange and regulatory guidance documents, and reasonable sensitivity to potential negative investor reaction to such news and neither Party shall make any other public announcement or statement, whether oral or written, concerning the termination of this Agreement without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed.

(iii) Notwithstanding anything to the contrary in this Section 10.4 and subject to Section 10.5, the Parties have the right to publicly disclose (A) the achievement of milestones under this Agreement; and (B) the commencement, completion, material data and key results of Clinical Trials conducted under this Agreement. After a publication has been made available to the public, each Party may post such publication or a link to it on its corporate web site without the prior written consent of the other Party.

(b) **Filing of this Agreement.** The Parties shall coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the SEC or any stock exchange or governmental agency on which securities issued by a Party or its Affiliate are traded, and each Party will use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; provided that each Party will ultimately retain control over what information to disclose to the SEC or any stock exchange or other governmental agency, as the case may be, and provided further that the Parties will use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither Party (nor its Affiliates) will be obligated to consult with or obtain approval from the other Party with respect to any filings to the SEC or any stock exchange or other governmental agency.

10.5 Publication. If either Party proposes to publicly present or publish in any publication or venue, in their respective Territories, any Clinical Trial data, non-clinical data or any associated results or conclusions generated by or on behalf of Licensee pursuant to Clinical Trials (each such proposed presentation or publication, a “**Proposed Publication**”), it shall obtain the other Party’s prior written consent and otherwise comply with this Section 10.5. The proposing Party shall provide the other Party with a copy of such Proposed Publication at least [***] days prior to the earlier of its presentation or intended submission for publication; provided that in the case of abstracts, this period shall be at least [***] Days (such applicable period, the “**Review Period**”). The proposing Party agrees that it will not submit or present any Proposed Publication (i) until the other Party has provided written comments during such Review Period on the material in such Proposed Publication, or (ii) until the applicable Review Period (as may be extended by subsection (C) below) has elapsed without written comments from the other Party, in which case the proposing Party may proceed and the Proposed Publication will be considered approved in its entirety. If the proposing Party receives written comments from the other Party during the applicable Review Period, it shall consider the comments of the other Party in good faith, but will retain the sole authority to submit the manuscript for such Proposed Publication; provided that the proposing Party agrees to (A) delete any Confidential Information of the other Party that the other Party identifies for deletion in the other Party’s written comments, (B) delete any Clinical Trial data, non-clinical data, results, conclusions or other related information that is not specific to or resulting from any Clinical Trial conducted in the proposing Party’s territory, and (C) delay such Proposed Publication for a period of up

to an additional [***] days after the end of the applicable Review Period to enable the other Party to draft and file patents with respect to any subject matter to be made public in such Proposed Publication and to which the other Party has the applicable intellectual property rights to file such patents. The proposing Party shall provide the other Party a copy of the Proposed Publication at the time of the submission or presentation. The proposing Party shall require its Affiliates, (sub)licensees (in case that Duality is the proposing Party), Sublicensees (in case that Licensee is the proposing Party) and contractors to comply with the obligations of this Section 10.5 as if they were the proposing Party, and shall be liable for their non-compliance.

10.6 Publication and Listing of Clinical Trials. Each Party agrees to comply, with respect to the listing of Clinical Trials or the publication of Clinical Trial information and results with respect to Licensed Products and to the extent applicable to its activities conducted under this Agreement, with any Applicable Law or applicable court order, stipulations, consent agreements and settlements entered into by such Party; provided that any listings or publications made pursuant to this Section 10.6 shall be considered a publication hereunder and shall be subject to Section 10.5.

10.7 Prior Non-Disclosure Agreement. As of the Effective Date, the terms of this Article 10 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) to the extent dealing with the subject of this Agreement. Any information disclosed pursuant to any such prior agreement relating to the subject to this Agreement shall be deemed Confidential Information for purposes of this Agreement.

10.8 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that would result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages would not be a sufficient remedy for any breach of this Article 10. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 10.

Article 11 REPRESENTATIONS AND WARRANTIES; LIMITATION OF LIABILITY

11.1 Mutual Representations and Warranties. Each Party represents and warrants to the other that, as of the Effective Date:

- (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof;
- (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action;
- (c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not (i) conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, (ii) conflict with or result in a breach of any provision of its

organizational documents, or (iii) violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and

(d) each Party shall conduct, and shall cause its Affiliates and sublicensees to conduct all activities under this Agreement in compliance with all Applicable Laws, all applicable national and international guidelines and any Regulatory Authority and Governmental Authority health care programs having jurisdiction, each as may be amended from time to time.

11.2 Additional Duality Representations and Warranties. Duality represents and warrants to Licensee, as of the Effective Date (solely with respect to the Licensed Products) and as of the date of delivery to Licensee of the data package in accordance with Section 2.7(d) (“**Option Package Delivery Date**”) (solely with respect to the Duality Immune Agonist ADC Product) as expressly set out below in this Section 11.2.

With respect to the [***], the below representations and warranties regarding Licensed Products are given as of the Effective Date but only specifically in relation to [***].

With respect to the [***], the below representations and warranties regarding Licensed Products are given as of the Effective Date but only specifically in relation to [***].

[***]

11.3 Additional Licensee Representations and Warranties. Licensee represents and warrants to Duality, as of the Effective Date:

[***]

11.4 Mutual Covenants. In addition to any covenants made by the Parties elsewhere in this Agreement, each Party hereby covenants to the other that:

(a) (i) all patient authorizations and consents required under Applicable Laws (in connection with any applicable clinical study) permit the granting of access of Data that such Party is required to provide to the other Party pursuant to Section 5.6, and (ii) it will comply with Applicable Laws in transferring personal and other Data in connection with the granting of access of Data that such Party is required to provide to the other Party pursuant to Section 5.6. Each Party will obtain all the necessary authorizations, consents and approvals in order for such Party to grant access to its Data with the other Party, including obtaining the necessary patient authorizations and consents, and obtaining the necessary approvals from and completing all necessary filing procedures with the applicable Governmental Authorities in the Territory and within the Retained Territory (to the extent required to preserve Licensee’s position in the Territory);

(b) it will not knowingly, during the Term, employ or use the services of any person who is debarred or disqualified in connection with activities relating to the Licensed Compound or Licensed Products; and in the event that it becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to it with respect to any activities relating to the Licensed Compound or Licensed Products, it will immediately notify the other Party in writing and it will cease employing,

contracting with, or retaining any such person to perform any services relating to the Licensed Compound or Licensed Products;

(c) it shall conduct, and shall cause its Affiliates, subcontractors, Sublicensees (in case of Licensee) or sublicensees (in case of Duality) to conduct all activities under this Agreement (including, as set forth in the Development Plan(s) with respect to the Licensed Products in the Field in the Territory) in compliance with all Applicable Laws, and any Regulatory Authority and Governmental Authority health care programs having jurisdiction, each as may be amended from time to time;

(d) it shall conduct its obligations with respect to Development of Licensed Products in the Territory in adherence with the Development Plan as may be amended from time to time;

(e) it shall comply, and ensure that shall use commercially reasonable efforts to cause its Affiliates, subcontractors and Sublicensees (in case of Licensee) or sublicensees (in case of Duality) to comply with and commit to uphold the ABC Terms in the performance of activities under this Agreement;

(f) it shall have (and shall ensure its Affiliates and (sub)licensees, and subcontractors as applicable, have), at all times, a reasonably sufficient number of suitably qualified personnel to allow the Party (or its Affiliates, sublicensees or subcontractors, as applicable) to conduct, in compliance with all Development timeframes set out in the applicable Development Plans and GXPs, any Clinical Trials that the Party is required to conduct with respect to the Licensed Products in its territory, or in the other Party's territory as permitted under this Agreement; and

(g) it shall not induce or solicit, or attempt to induce or solicit, any employees of the other Party or any of its Affiliates to leave the employment of, or to terminate his/her employment, services or engagement with, the other Party or its applicable Affiliate, or enter into any employment or services agreement or arrangement with such Party or any of its Affiliates.

11.5 Duality Covenants. In addition to any covenants made by Duality elsewhere in this Agreement, Duality hereby covenants to Licensee as follows:

[***]

11.6 Performance by Affiliates, Sublicensees and Subcontractors. (a) Subject to Licensee's prior written consent or if explicitly stated in the Development Plan or this Agreement, Duality may perform some or all of its respective obligations under this Agreement through one or more Affiliates, subcontractors or sublicensees; and (b) Licensee may perform some or all of its respective obligations under this Agreement through one or more Affiliates, subcontractors or Sublicensees; provided that with respect to the foregoing clauses (a) and (b), the Party involving its Affiliates, subcontractors or Sublicensees (in case of Licensee) or sublicensees (in case of Duality) shall at all times be fully responsible for the performance and payment of such Affiliate, subcontractor or Sublicensees (in case of Licensee) or sublicensees (in case of Duality).

11.7 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS

PROVIDED BY DUALITY TO LICENSEE HEREUNDER ARE PROVIDED “AS IS,” AND DUALITY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OBTAINING SUCCESSFUL RESULTS, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

Article 12
INTELLECTUAL PROPERTY

12.1 Ownership.

(a) **Background IP.** (i) Duality shall retain all right, title and interest in and to any Patents, Know-How, and other intellectual property rights Controlled by Duality or any of its Affiliates on or prior to the Effective Date or during the Term independent of the activities hereunder (“**Duality Background IP**”), and (ii) Licensee shall retain all right, title and interest in and to any Patents, Know-How, and other intellectual property rights Controlled (other than pursuant to this Agreement) by Licensee or any of its Affiliates on or prior to the Effective Date or during the Term independent of the activities hereunder, specifically relating to ADC (the “**Licensee Background IP**”).

(b) **Solely Owned Collaboration IP and Solely Owned Collaboration Patents.**

[***]

(c) [***]

(d) [***]

(e) [***]

(f) [***]

(g) **Data and Regulatory Materials.** Notwithstanding anything contrary in this Section 12.1, the ownership rights to Regulatory Materials are allocated in accordance with Sections 5.2(b) and 5.4. The ownership rights to Data are allocated in accordance with Section 5.6(a).

(h) [***]

(i) **Disclosures; Cooperation.** Each Party shall, and shall ensure that each of its Affiliates, (sub)licensees (in the case of Duality), Sublicensees (in the case of Licensee) and subcontractors under this Agreement has a contractual obligation to disclose to such Party all Collaboration IP, Data and other Know-How generated, invented, discovered, developed, made or otherwise created by or for them or their employees, agents or independent contractors, and to provide sufficient documentary proof to evidence ownership, rights and interest with respect thereto, so that such Party can comply with its obligations under this Section 12.1.

(j) **Inventorship Determination.** The Parties agree that [***].

12.2 Patent Prosecution and Maintenance.

(a) **Definition.** For purposes of this Section 12.2, the terms “prosecute,” “prosecuting” and “prosecution,” when used in reference to any Patent, shall be deemed to include, without limitation, [***] with respect to such Patent.

- (b) [***]
- (c) [***]
- (d) [***]
- (e) [***]
- (f) [***]
- (g) [***]

12.3 Infringement by Third Parties.

(a) **Notice.** In the event that either Duality or Licensee becomes aware of any infringement or threatened infringement by a Third Party of any Solely Owned Collaboration Patent, Duality Product Patent, Duality Linker-Payload Patent, [***] any related declaratory judgment or equivalent action, including administrative proceedings, alleging the invalidity, unenforceability or non-infringement of any such Patent, it shall notify the other Party in writing to that effect.

- (b) [***]
- (c) [***]
- (d) [***]
- (e) [***]
- (f) [***]

12.4 Infringement of Third Party Rights.

[***]

12.5 Marking. [***]

12.6 Patent Listings. On a Licensed Product-by-Licensed Product basis, as between the Parties, [***] to make all patent listings of Duality Product Patents, Solely Owned Collaboration Patents, [***] or other patent-related submissions with Regulatory Authorities with respect to such Licensed Product, except for Duality Linker-Payload Patents [***], [***] to make all patent listings *provided that* [***] will be obliged to make all patent listings or other patent-related submissions with Regulatory Authorities in [***]. [***] reasonable requests in connection therewith,

including meeting any submission deadlines, to the extent required or permitted by Applicable Laws.

12.7 Patent Right Term Extension. [*]**

**Article 13
TERM; TERMINATION**

13.1 Term. The term of this Agreement (the “**Term**”) shall commence on the Effective Date, and unless terminated earlier as provided in this Article 13, shall continue in full force and effect, on [***] except as provided otherwise in this Article 13.

13.2 [*]**

13.3 Termination for Material Breach by Either Party.

(a) **Termination Right.** A Party shall have the right to terminate this Agreement (in its entirety or on a Licensed Product-by-Licensed Product and country-by-country basis) upon written notice to the other Party if such other Party is in material breach of this Agreement and has not cured such breach within [***] days after written notice from the terminating Party requesting cure of the breach. In case the alleged material breach is a material breach of Licensee’s diligence obligations set forth in Sections 4.1 and/or 7.1 of this Agreement, Duality shall only be entitled to terminate the Agreement with effect to the country or countries with respect to which Licensee has in fact materially breached the diligence obligations with respect to the Original ADC Licensed Product and not cured such breach, If at the end of the cure period the breaching Party has failed to perform the activities of the cure plan to cure the breach, the non-breaching Party shall be entitled to terminate the Agreement with [***] prior notice. If the existence of material breach or the failure to cure such material breach is not disputed by the breaching Party and the Agreement is terminated by the non-breaching Party, the consequences of termination set forth in Section 13.7 or 13.8 (as the case may be) shall apply. If the existence of material breach or the failure to cure such material breach is disputed by the breaching Party, Section 13.7 or 13.8 (as the case may be) shall apply if the existence of material breach or the failure to cure such material breach is determined pursuant to Section 15.2 and the Agreement is thereafter terminated by the breaching Party.

(b) **Dispute as to Material Breach.** In the event that the breaching Party disputes the existence of material breach or the failure to cure such material breach by initiating arbitration proceedings pursuant to Section 15.2 within the cure period, the non-breaching Party shall not have the right to terminate in accordance with Section 13.3(a) unless and until the relevant dispute has been resolved pursuant to Section 15.2. During the pendency of such dispute, the applicable cure period shall be tolled, all the terms of this Agreement shall remain in effect, and the Parties shall continue to perform all of their respective obligations hereunder.

13.4 Termination for Other Causes.

(a) [***]

(b) **Bankruptcy.** A Party shall have the right to terminate this Agreement upon written notice to the other Party upon the filing or institution of bankruptcy, reorganization, dissolution, liquidation or winding up of such other Party, or the making or seeking to make or arrange an assignment of a substantial portion of such other Party's assets for the benefit of creditors of such other Party, or the initiation of proceedings in voluntary or involuntary bankruptcy against such other Party, or is adjudged bankrupt, or the appointment of a receiver or trustee of such other Party's property, in each case that is not discharged within [***] days, or immediately upon written notice to the Party, if such Party otherwise admits to the other Party in writing its inability generally to meet its obligations as and when they fall due in the general course of business. In the event a Party is bankrupted or a bankruptcy proceedings is commenced by or against such Party or its Affiliates or any country or jurisdiction, all rights under this Agreement will be fully exercisable and the bankrupt Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall continue to perform all of the obligations provided in this Agreement to be performed by such Party. If the bankrupt Party and its successors and assigns are restricted by Applicable Laws from performing its obligations hereunder and the other Party elects to retain its rights hereunder, then the bankrupt Party shall provide to the other Party copies of all information necessary for such other Party to prosecute, maintain and enjoy its rights under the terms of this Agreement promptly upon such other Party's written request therefor. All rights, powers and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity.

(c) [***]

(d) **Mutual Agreement.** The Parties may terminate this Agreement in full or on a Licensed Product-by-Licensed Product or a country-by-country basis, at any time during the Term upon mutual agreement in writing.

13.5 General Effects of Expiration or Termination.

(a) **Accrued Rights and Obligations.** Neither expiration nor any termination of this Agreement for whatsoever reason shall relieve either Party of any obligation or liability (including but not limited to any payment obligation under Article 8) accruing prior to such expiration or termination, nor shall expiration or any termination of this Agreement for whatsoever reason preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement. Such obligations and rights shall survive termination and expiration of this Agreement.

(b) **Termination of non-expired Options.** In case of termination of the entire Agreement, all non-expired option periods under the Agreement shall automatically terminate. Upon termination of one or more Licensed Products, the option period shall only terminate with respect to the terminated Licensed Products.

(c) **Surviving Terms.** The Parties' rights and obligations under Articles 1 (Definitions), 8 (Financial Terms) unless otherwise set out in this Article 13 the Financial Terms only survive in accordance with the respective applicable terms with respect to Licensee's sell-off right in Sections 13.6(e), 13.7(b)(iv) and 13.8(b)(iii)), Article 9 (Payment), Article 10 (Confidentiality),

Section 12.1 and with respect to [***] only, Sections 12.2 and 12.4, Sections 13.5 to 13.10, Article 14 (Indemnification and Insurance), Article 15 (Dispute Resolution) and Article 16 (Miscellaneous) of this Agreement shall survive expiration or any termination of this Agreement.

13.6 [***]

13.7 Consequences of Termination by Duality for Material Breach or Patent Challenge by Licensee. If an arbitration tribunal in accordance with the process set out in Section 15.2 confirmed the existence of a material breach on the part of Licensee, and such material breach was not or cannot be cured, or in case of an uncured patent challenge by Licensee (Section 13.4(a)(i)), the following shall apply:

(a) **Duality's Election to Continue.** [***]

(b) **Duality's Election to Terminate.** Duality may, in its sole discretion, elect to terminate the Agreement (in part or in its entirety, as applicable) for material breach in accordance with Section 13.3. The consequences of such a termination for material breach shall be as follows:

(i) **Licenses Granted to Licensee.** In case of a termination of the entire Agreement, [***].

(ii) **Rights Granted to Duality.** In case of termination of the entire Agreement, [***].

(iii) **Wind-Down or Transfer of Activities.** Licensee shall, as directed by Duality in its sole discretion on a Clinical Trial-by-Clinical Trial basis, either:

[***]

(iv) [***]

(v) **Sublicenses.** Duality shall grant to Licensee's or Licensee's Affiliate's Sublicensees a direct license, provided that (A) such sublicense agreement is consistent with the relevant terms and conditions of this Agreement at the time of termination of this Agreement, (B) such Sublicensee then is not in material breach of its sublicense agreement and (C) such Sublicensee then has not caused Licensee to be in material breach of this Agreement due to any act or omission of such Sublicensee. The scope of such direct license shall be no less than the scope of the license granted in this Agreement and sublicensed to such Sublicensee and such direct license shall be on terms and conditions substantially similar to those set forth in this Agreement.

13.8 Consequences of Termination by Licensee for Material Breach or Patent Challenge by Duality. If an arbitration tribunal in accordance with the process set out in Section 15.2 confirmed (A) the existence of a material breach on the part of Duality, and such material breach was not or cannot be cured, or (B) in case of [***], with the Licensee's Executive Officer having the final say, the following shall apply:

[***]

13.9 [***]

13.10 [***]

Article 14 INDEMNIFICATION

14.1 Indemnification of Duality. Licensee shall indemnify and hold harmless each of Duality and its Affiliates and their respective directors, officers, employees, consultants, agents and successors and assigns of any of the foregoing (the “**Duality Indemnitees**”) from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys’ fees (“**Losses**”), incurred by any Duality Indemnitee as a result of any claims, demands, actions, suits or proceedings brought by a Third Party (“**Third Party Claims**”) arising directly or indirectly out of: (a) the practice by Licensee or its Affiliates or Sublicensees or subcontractors of the license in Section 2.1; (b) the research, Development, Manufacture or have Manufactured, use, handling, storage, Commercialization or other disposition of the Licensed Compound or the Licensed Products by Licensee or its Affiliates or Sublicensees or subcontractors; (c) the negligence or willful misconduct of any Licensee Indemnitee; or (d) any breach of any representations, warranties or covenants by Licensee under this Agreement; except, in each case, (x) to the extent such Third Party Claims fall within the scope of the indemnification obligations of Duality set forth in Section 14.2, or (y) arising from or occurring as a result of a Duality Indemnitee’s negligence, illegal conduct or willful misconduct in performing its or their obligations or exercising their rights under this Agreement. Licensee’s indemnification obligation specifically excludes any and all Third Party Claims, including but not limited the payment of royalties, that relate to or are incurred by the use of the Duality Licensed IP by Licensee, its Affiliates and/or Sublicensees under this Agreement and that result from Third Party Agreements of Duality or Duality’s Affiliates existing at the Effective Date.

14.2 Indemnification of Licensee. Duality shall indemnify and hold harmless each of Licensee and its Affiliates and their respective directors, officers, employees, consultants, agents and successors and assigns of any of the foregoing (the “**Licensee Indemnitees**”), from and against any and all Losses incurred by any Licensee Indemnitee as a result of any Third Party Claims arising directly or indirectly out of: (a) the practice by Duality or its Affiliates or sublicensees or subcontractors of the license granted to Duality under Section 2.5; (b) the Development, Manufacture, use, handling, storage, sale or other disposition of the Licensed Compound or Licensed Products by Duality or its Affiliates or sublicensees or subcontractors; (c) the negligence or willful misconduct of any Duality Indemnitee; or (d) any breach of any representations, warranties or covenants by Duality under this Agreement; except, in each case, (x) to the extent such Third Party Claims fall within the scope of the indemnification obligations of Licensee set forth in Section 14.1 or (y) arising from or occurring as a result of a Licensee Indemnitee’s negligence, illegal conduct or willful misconduct in performing its or their obligations or exercising their rights under this Agreement. In addition to the above, and not subject to (x), regardless of any information provided by Duality to Licensee regarding agreements with Third Parties entered into prior to the Effective Date, Duality’s indemnification obligation shall cover any and all Third Party Claims, including but not limited to the payment of royalties, (a) that relate to or are incurred by the use of the Duality Licensed IP by Licensee, its Affiliates and/or Sublicensees under this Agreement and (b) that result from such Third Party agreements of Duality or Duality’s Affiliates existing at the Effective Date.

14.3 Procedure. If any Duality Indemnitee or Licensee Indemnitee intends to claim indemnification under this Article 14 (the “**Indemnitee**”), Duality or Licensee, as the case may be, shall promptly notify the indemnifying Party (the “**Indemnitor**”) in

writing of any Third Party Claim, in respect of which the Indemnitee intends to claim such indemnification. Each indemnification claim notice must contain a description of the claim, the nature and amount of such loss (to the extent known at the time). The Indemnitor shall have sole control of the defense and/or settlement thereof and the Indemnitee shall be entitled to participate in (but not control) the defence of such Third Party Claim and to employ counsel of its choice for this purpose, at its own expense. The indemnity arrangement in this Article 14 shall not apply to amounts paid in settlement of any action with respect to a Third Party Claim, if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld or delayed unreasonably. The failure to deliver written notice to the Indemnitee within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the Indemnitor of its indemnification obligations under this Article 14 if and to the extent the Indemnitee is actually prejudiced thereby. Duality or Licensee, as the case may be, and the Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Third Party Claim covered by these indemnification provisions. The Indemnitor shall not settle any Third Party Claim without the prior written consent of the Indemnitee if the settlement is reasonably expected to: (a) result in or impose any obligation (including any payment obligation) on the Indemnitee or otherwise adversely affect the business of the Indemnitee in any manner, or (b) result in any admission of wrong-doing or fault by the Indemnitee. The costs and expenses, including fees and disbursements of counsel, incurred by the Indemnitee in connection with any claim shall be reimbursed by the Indemnitor on a calendar quarter basis, without prejudice to the Indemnitor's right to contest the Indemnitee's right to indemnification and subject to refund in the event the Indemnitee is ultimately held not to be obligated to indemnify the Indemnitee.

14.4 Insurance. Each Party, at its own expense, shall maintain product liability and other appropriate insurance (or self-insure) in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement during the Term. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request. Such insurance shall not be construed to create a limit on either Party's liability with respect to its indemnification obligations under this Article 14.

14.5 [***]

Article 15 DISPUTE RESOLUTION

15.1 Deadlock Resolution. In the event a deadlock occurs with respect to the decision-making process of the JSC, such deadlock shall be subject to binding determination by an expert panel in the Hong Kong Special Administrative Region. The expert panel shall consist of [***] members, [***] of which [***] appointed by each Party and the [***] member shall be selected by the other [***] members (collectively, the “**Experts**”). The panel must be appointed within [***] days of the occurrence of a deadlock event or such longer period as the Parties may agree. Each Expert shall be a person having not less than [***] years' experience in the area of expertise in the business of pharmaceuticals (including biologics) and having no conflict of interest with either Party. If the issues in dispute involve scientific, technical or commercial matters, the experts chosen hereunder shall have educational training or industry experience sufficient to demonstrate a reasonable level of relevant scientific, medical

and industry knowledge, as necessary to resolve the dispute. With respect to any dispute to be submitted to an Expert pursuant to this Agreement, the use of the Expert shall be the exclusive remedy of the Parties, and neither Party shall attempt to adjudicate such dispute in any other forum. The decision of the Experts shall be final and binding on the applicable Parties involved in such dispute and deadlock resolution procedure contemplated by this Section 15.1 and shall not be capable of challenge, whether by arbitration, in court or otherwise. All proceedings and communications shall be in English.

15.2 Disputes. Subject to Sections 15.4 and 15.5, upon the written request of either Party to the other Party, any differences, claim, dispute, or controversy as to the breach, enforcement, interpretation or validity of this Agreement (a “**Dispute**”) shall be referred to the Executive Officers for resolution. In the event such executives are unable to resolve such Dispute within [***] days after the initial written request, then, upon the written demand of either Party and subject to Section 15.4 below, the Dispute shall be referred to and finally resolved by binding arbitration administered by the Hong Kong International Arbitration Centre (“**HKIAC**”) (or any successor entity thereto) pursuant to the United Nations Commission on International Trade Law (“**UNCITRAL**”) Arbitration Rules in force when the notice of arbitration is submitted, as modified by the HKIAC Procedures for the Administration of Arbitration under the UNCITRAL Arbitration Rules (the “**Rules**”), as modified by Section 15.3 below.

15.3 Arbitration.

(a) **Procedure.** The arbitration shall be conducted by a panel of three arbitrators experienced in the business of pharmaceuticals (including biologicals). If the issues in dispute involve scientific, technical or commercial matters, the arbitrators chosen hereunder shall engage experts having educational training or industry experience sufficient to demonstrate a reasonable level of relevant scientific, medical and industry knowledge, as necessary to resolve the dispute. Within [***] days after initiation of arbitration, each of the Parties shall select one arbitrator and these two arbitrators shall jointly select a third arbitrator. If a Party fails to select an arbitrator or if the two arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator within such [***] day period, any unselected arbitrator or third arbitrator, as the case may be, shall be appointed in accordance with the Rules. The place of arbitration and the seat of arbitration shall be Hong Kong Special Administrative Region, and all proceedings and communications shall be in English. Unless agreed by the Parties in writing, all documents provided under or in connection with this Agreement shall be in the English language or accompanied by a certified English translation. If such document is translated into any other language, the English language version shall prevail unless the document is a constitution, statutory or other official document. The laws governing this arbitration agreement shall be the laws of Hong Kong Special Administrative Region and the arbitral award shall be final and binding on the Parties. Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor the arbitrators may disclose the existence, content, or results of arbitration without the prior written consent of both Parties.

(b) **Arbitrators’ Award.** The arbitrators shall, within [***] days after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The

decision or award rendered by the arbitrators shall be final and non-appealable, and judgment may be entered upon it in any court of competent jurisdiction.

(c) **Costs.** Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators; provided, however, that the arbitrators shall be authorized to determine whether a Party is the prevailing party, and if so, to award to that prevailing party reimbursement for any or all of its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, etc.), and/or the fees and costs of the HKIAC and the arbitrator.

(d) **Protective Orders.** At the request of either Party, the Tribunal shall enter an appropriate protective order to maintain the confidentiality of information produced or exchanged in the course of the arbitration proceedings.

15.4 [***]

15.5 Interim Relief. Each Party shall be entitled to take action in any court with competent jurisdiction to apply for and be granted emergency or other interim relief and otherwise enforce by injunction, specific performance or other equitable relief, without prejudice to any other rights and remedies that it may have under this Agreement.

15.6 Continued Performance. Provided that this Agreement has not been terminated in its entirety, the Parties agree to continue performing under this Agreement in accordance with its provisions, pending the final resolution of any Dispute.

Article 16 MISCELLANEOUS

16.1 Governing Law. This Agreement and any disputes, claims, or actions related thereto shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflicts of law provisions thereof.

16.2 Entire Agreement; Amendment. This Agreement, including the Schedules hereto, sets forth all of the agreements and understandings between the Parties with respect to the subject matter hereof and thereof, and supersedes and terminates all prior agreements and understandings between the Parties with respect to the subject matter hereof and thereof. There are no other agreements or understandings with respect to the subject matter hereof, either oral or written, between the Parties. Except as expressly set forth in this Agreement, no subsequent amendment, modification or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.

16.3 Further Assurances. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as any other Party may reasonably

request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

16.4 Relationship Between the Parties. The Parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship or legal entity of any type between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever. Neither Party shall treat or report the relationship arising under this Agreement as a partnership for United States tax purposes unless otherwise required pursuant to a determination within the meaning of Section 1313 of the Internal Revenue Code of 1986, as amended.

16.5 Non-Waiver. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and of a particular scope, and shall be signed by such Party.

16.6 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned by a Party without the prior written consent of the other Party (which shall not be unreasonably withheld, conditioned or delayed), except to (a) an Affiliate; provided that this Agreement shall be assigned in whole, and the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate; (b) a Third Party in connection with the sale of all or substantially all of its assets to which this Agreement relates, whether in a sale of stock, sale of assets, business combination, reorganization, or other transaction or series of related transactions. Unless expressly stated otherwise in this Agreement, Duality may assign without the prior consent of Licensee its right to receive payments under this Agreement or grant any security interest in its rights, title and interest in this Agreement, in whole or in part and in their entirety or in portions, to an institutional financier in connection with a financing transaction; provided that Duality has given Licensee a prior written notice regarding such assignment. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the permitted assigns of the Parties. Any assignment not in accordance with this Agreement shall be void.

16.7 Third Party Beneficiaries. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including any third party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby.

16.8 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part. The Parties shall use their commercially reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and

enforceable provision(s) in a way that, to the extent practicable and legally permissible, implements the original intent of the Parties.

16.9 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by any method of mail (postage prepaid) requiring return receipt, or by overnight courier or facsimile confirmed thereafter by any of the foregoing, to the Party to be notified at its address(es) given below, or at any address such Party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; (b) if delivered by overnight courier, [***] Business Days after delivery; or (c) if sent by facsimile, upon electronic confirmation of receipt.

if to Duality:	Duality Biologics (Suzhou) Co., Ltd Unit 1106, No 868 Yinghua Road, Pudong New District, Shanghai, China Attention: [***] Email: [***]
with a copy to:	[***] [***] [***] [***] [***] [***]
if to Licensee:	BIONTECH SE [***] Address: An der Goldgrube 12, 55131 Mainz, Germany
with a copy to:	Email: [***]

16.10 Force Majeure. Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such Party's reasonable control including but not limited to acts of God, fire, flood, explosion, earthquake, or other natural forces, regional or worldwide epidemic, pandemic, war, civil unrest, acts of terrorism, accident, destruction or other casualty, and a material change in Applicable Law (a "**Force Majeure Event**"). Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused such event(s) to occur. Notice of a Party's failure or delay in performance due to a Force Majeure Event must be given to the other Party within [***] days after its occurrence. The Party affected by a Force Majeure Event will use reasonable efforts to resume performance of its obligations and will keep the other Party informed of actions related thereto. If any such failure or delay in a Party's performance hereunder continues for

more than [***] days, the other Party may terminate this Agreement upon written notice to the delayed Party.

16.11 Interpretation. The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. The words “include”, “including”, “containing”, “comprising” and similar words shall not be deemed to be terms of limitation and shall be deemed to be followed by “without limitation,” whether or not specifically stated, and the language following such words shall not be deemed to set forth an exhaustive list. The word “or” means “and/or” unless the context dictates otherwise because the subject of the conjunction are mutually exclusive. The words “herein,” “hereof” and “hereunder” and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. The words “pharmaceuticals” or “drugs” include biologics unless expressly indicated otherwise. All references to days in this Agreement shall mean calendar days, unless otherwise specified. All references to any Applicable Law in this Agreement shall mean such Applicable Law as amended, restated, supplanted or otherwise modified from time to time. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist.

16.12 Construction. The Parties hereto acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in a favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

16.13 Counterparts; Electronic Signatures. This Agreement may be executed in two (2) or more counterparts, including by transmission of facsimile or PDF copies of signature pages to the Parties or their representative legal counsel, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one and the same instrument. Electronic, facsimile or PDF image signatures shall be treated as original signatures, with the understanding that each Party expressly agrees that such Party shall be bound by its own electronically transmitted signature and shall accept the electronically transmitted signature of the other Party (including through the use of eSignature platforms such as DocuSign®). No Party will raise the use of electronic delivery to transmit a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of electronic delivery as a defense to the formation of a contract.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

In Witness Whereof, the Parties hereto have duly executed this **License and Collaboration Agreement** as of the Effective Date.

Duality Biologics (Suzhou) Co., Ltd.

By: /s/ Zhongyuan John Zhu
Name: Zhongyuan John Zhu
Title: Chief Executive Officer

BioNTech SE

By: /s/ Ugur Sahin
Name: Ugur Sahin
Title: Chief Executive Officer

By: /s/ Sean Marett
Name: Sean Marett
Title: Chief Business Officer and Chief Commercial Officer

Schedule 1.1

ABC Terms

1. Each Party agrees that it will not undertake any activities which will result in a violation of any applicable laws, regulations, and applicable industry and professional codes, including but not limited to applicable local and extraterritorial anti-bribery, Anti-Corruption Laws and anti-money laundering laws (collectively "**Prohibited Conduct**") in connection with the performance of any activities under this Agreement.
2. In particular, each Party agrees that during the course of the performance of activities under this Agreement, it (i) shall not make any offer, payment, or promise to pay money or provide anything of value to a Government Official (as defined below) or any other individual and/or legal entity whether directly or indirectly, for the purpose of improperly influencing any act and/or decision of, and/or for securing any improper advantage; (ii) shall not accept, receive, agree to accept and/or receive a payment and/or anything of value from any individual for undue favorable treatment in obtaining, retaining, and/or directing business for, and/or to obtain any undue special concession on behalf of either Party; and (iii) shall not facilitate any payments to any Government Official to expedite a routine government action and/or other official act.

The term "**Government Official**" shall include (i) individuals acting on behalf of governments on a national, regional and local level (such as elected officials, customs officials, tax officials, etc.); (ii) individuals acting on behalf of government-owned or government-controlled enterprises; (iii) individuals acting for political parties or as or on behalf of candidates for public office; and (iv) individuals acting on behalf of public international organizations (such as the WHO, World Bank, OECD, etc.).

3. All transactions and expenses incurred on behalf of either Party shall be accurately recorded and maintained in the respective Party's books and records in a timely manner and in reasonable detail in accordance with the applicable generally accepted accounting principles. False, misleading, incomplete, duplicated, inaccurate or artificial entries for the foregoing expenses in a Party's books and records are strictly prohibited.
4. Each Party agrees that if it becomes aware or has reason to suspect that any person or legal entity acting on the Party's and/or the other Party's behalf has engaged in any Prohibited Conduct related to the Agreement, then such Party will promptly report such knowledge or suspicion to the other Party via the following email address: (a) in case that Duality is the reporting party: [***] and (b) in case that Licensee is the reporting party: [***].
5. Duality shall apply Commercially Reasonable Efforts to implement, operate and enforce, without undue delay after the Effective Date, a reasonably designed compliance and business ethics management and control system that is intended for the prevention and detection of criminal conduct in accordance with applicable Anti-Corruption Laws.

6. Each Party agrees to provide reasonable cooperation in any investigation that may be conducted by or on behalf of the other Party related to the performance of potentially Prohibited Conduct as described in Article 1 above. Upon notice of an intended investigation, a Party will provide, in a reasonable time, to the investigating Party or to a third party engaged by the investigating Party: (a) access to the relevant persons; and/or (b) access to relevant documents and data (e.g., invoices and requests for expense reimbursement, supporting receipts and substantiation, and original entry records for charges and payments).
7. Each Party acknowledges that the obligations under the applicable local and extraterritorial anti-bribery, Anti-Corruption Laws and anti-money laundering laws apply to all its Affiliates and employees, subcontractors and Sublicensees (in case of Licensee) or sublicensees (in case of Duality). Each Party will bind subcontractors who act for or on behalf of such Party to perform activities under this Agreement by such Party for or on behalf of the other Party by respective contractual clauses encompassing all or all material provisions of this Schedule.

Schedule 1.46

Description of Duality Know-How

[***]

Schedule 1.55
List of Duality Patents

[***]

Schedule 1.89
List of Indications

[***]

Schedule 2.6

Initial Know-How Transfer

[***]

Schedule 4.6
Agreed Preparatory Activities for Initiation of a [*] Clinical Trial**

[***]

Schedule 10.4
Joint Press Release

[***]

*** Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) the type of information that the Registrant treats as private or confidential.

*Execution Version
Confidential*

LICENSE AND COLLABORATION AGREEMENT

by and between

DUALITY BIOLOGICS (SUZHOU) CO. LTD.

and

BIONTECH SE

dated as of March 31, 2023

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LICENSE AND COLLABORATION AGREEMENT

This License and Collaboration Agreement (the “**Agreement**”) is entered into as of March 31, 2023 (the “**Effective Date**”), by and between **Duality Biologics (Suzhou) Co. Ltd.**, a corporation organized and existing under the laws of the People’s Republic of China (“**Duality**”), having a place of business at Unit 1105-1106, No 868 Ying Hua Road, Pudong New District, Shanghai, China, and **BioNTech SE**, a company organized and existing under the laws of Germany, having a place of business at An der Goldgrube 12, D-55131 Mainz, Germany (“**Licensee**”).

Recitals

Whereas, Duality is a clinical stage company focusing on the discovery and development of the next generation ADC therapeutics to treat patients in cancer and autoimmune diseases;

Whereas, Licensee is engaged in the research, development and commercialization of active immunotherapies for patient-specific approaches to the treatment of diseases;

Whereas, Licensee desires to obtain from Duality, and Duality desires to grant to Licensee, an exclusive sublicensable license under the Duality Licensed IP to Develop, Manufacture and Commercialize the ADC Licensed Products in the Field in the Territory (each as defined below), subject to the terms and conditions of this Agreement;

Whereas, Licensee desires to obtain from Duality, and Duality desires to grant to Licensee, an exclusive sublicensable license under the [***] In-Licensed IP to Develop, Manufacture and Commercialize the Sequence Licensed Products in the Field in the Territory (each as defined below), subject to the terms and conditions of this Agreement; and

Whereas, the Parties desire to collaborate in the Development, Manufacture and Commercialization of the Original ADC Licensed Products in accordance with the terms and conditions of this Agreement.

Now, Therefore, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Duality and Licensee hereby agree as follows:

ARTICLE 1 DEFINITIONS

1.1 “**ABC Terms**” shall mean those terms set out in **Schedule 1.1** of this Agreement.

1.2 “**Accounting Standards**” shall mean with respect to a Selling Party (as defined below), International Financial Reporting Standards endorsed by the European Union or other applicable standard accounting principles used by Sublicensees.

1.3 “**ADC**” shall mean any construct comprising an Antibody(ies) linked to a non-Antibody chemical species with a therapeutic or biological activity or function, including non-Antibody chemical species that (i) directly kills, slows or stops the growth of a tumor cell through such compound’s primary mechanism of action (“**Cytotoxic Payload**”) or (ii) [***].

1.4 “**ADC Licensed Product**” shall mean the Original ADC Licensed Product, [***] and [***], but excluding any Additional Active.

1.5 “**Additional Active(s)**” shall mean any active pharmaceutical or biologic ingredient(s) that is not the Licensed Compound.

1.6 “**Applicable Co-Promotional Law**” shall mean the Applicable Laws that are applicable to the marketing, promotion, distribution and sale of Co-Promotion Products, including (if applicable) the Federal Food, Drug and Cosmetic Act, the American Medical Association Guidelines on Gifts to Physicians from Industry and the Pharmaceutical Research and Manufacturers of America (“PhRMA”) Code on Interactions with Healthcare Professionals.

1.7 “**Adjusted Net Profits**” and, with correlative meaning, “**Adjusted Net Losses**”, shall mean, [***].

1.8 “**Affiliate**” shall mean any company or entity controlled by, controlling, or under common control with a Party or another entity. For the purpose of this definition, an entity shall be deemed to “**control**” another entity, if it owns directly or indirectly, more than fifty percent (50%) of the outstanding voting securities, capital stock, or other comparable equity or ownership interest of such entity, or possession, direct or indirect, of the power to direct or cause the direction of the management or policies of an entity (whether through ownership of securities or other ownership interests, by contract or otherwise).

1.9 “**Alliance Manager**” shall have the meaning provided in Section 3.9.

1.10 “**Annual Net Sales**” shall mean for a particular Licensed Product the total Net Sales for a particular Calendar Year.

1.11 “**Antibody**” shall mean any antibody (including murine, chimeric, human, humanized, recombinant, transgenic, grafted, phage display derived, or single chain antibody), or antigen binding fragment thereof. [***]

1.12 “**Anti-Corruption Laws**” shall mean all applicable anti-bribery and anti-corruption laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, the U.K. Bribery Act 2010 and the PRC Anti-Money Laundering Law and the comparable Applicable Laws of any countries in which candidates or Licensed Products, payments or services will be provided or procured under or pursuant to this Agreement.

1.13 “**Applicable Laws**” shall mean collectively the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, of any Governmental Authority and any license, franchise, permit or similar right granted under any of the foregoing (including Regulatory Approvals) and any policies and other requirements of or from any court, arbitrator, Regulatory Authority or governmental agency or Governmental Authority having jurisdiction over or related to the subject item or subject person, including all applicable GXPs, Anti-Corruption Laws, Applicable Data Protection Laws, accounting and recordkeeping laws, export control laws and laws relating to interactions with health care professionals and government officials.

1.14 “**Applicable Data Protection Law**” shall mean all Applicable Laws in any jurisdiction relating to privacy or the processing or protection of personal data or personal information, including the General Data Protection Regulation (EU) 2016/679 (GDPR), the UK Data Protection Act 2018, the e-Privacy Directive (2002/58/EC) and the comparable in other jurisdictions and all guidance issued by any applicable data protection authority.

1.15 “**B7H3**” shall mean [***].

1.16 “Biosimilar Product” shall mean with respect to a particular Licensed Product in a given country, a product comprising an ADC sold by a Third Party not authorized by Licensee or its Affiliates or Sublicensees that is approved by the applicable Regulatory Authority for such country through an application or submission filed with a Regulatory Authority for marketing approval of a biologic product claimed to be biosimilar or interchangeable to such Licensed Product, including an application filed under 42 U.S.C. § 262(k) (or any successor thereto) or any similar laws or regulations in a country outside the United States in reliance on data generated for a Regulatory Approval of such Licensed Product.

1.17 “Biologics License Application” or “BLA” shall mean an application requesting permission from the FDA to introduce, or deliver for introduction, a biological product into interstate commerce.

1.18 “Business Day” shall mean any day that is not a Saturday, a Sunday or any other day on which banks are required or authorized by law to close in Mainz, Rhineland-Palatine (in Germany) or any government mandated holiday in Mainland China.

1.19 “Calendar Quarter” shall mean each period of three (3) consecutive months commencing on January 1, April 1, July 1 or October 1 (or any portion thereof at the beginning or end of the Term or other relevant period).

1.20 “Calendar Year” shall mean each period of twelve (12) consecutive months commencing on January 1 and ending on December 31 (or any portion thereof at the beginning or end of the Term or other relevant period).

1.21 “Cell Lines and Cell Banks” shall have the meaning provided in Section 6.3.

1.22 “Change of Control” shall mean, with respect to either Party: (a) a merger, acquisition, reorganization, or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, acquisition, reorganization, or consolidation; (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner, directly or indirectly, of more than fifty percent (50%) of the combined voting power of the outstanding securities of such Party; or (c) a transfer to a Third Party of all or substantially all of its assets relating to this Agreement.

1.23 “Clinical Trial” shall mean a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, Registrational Trial or other human clinical trial conducted after the Regulatory Approval of a product in a country, which trial may be conducted to (a) enhance scientific knowledge of such product (e.g., for expansion of product labeling), (b) due to a request or requirement of a Regulatory Authority in such country, (c) is otherwise designed to establish that a product is reasonably safe for continued testing and to identify adverse reactions and ascertain the safety of the product, or (d) investigate the safety and efficacy of the product for its intended use, and to define warnings, precautions and adverse reactions that may be associated with the product in the dosage range to be prescribed.

1.24 “CMC” shall mean chemistry, manufacturing and controls with respect to the Licensed Compound or ADC Licensed Products.

1.25 “CMC Materials” shall have the meaning provided in Section 6.2.

1.26 “CMO” shall mean Third Party contract manufacturing organization.

- 1.27 “**Collaboration IP**” shall mean [***].
- 1.28 “**Co-Promote**” shall mean the Detailing and such other activities assigned to Duality in the Co-Promotion Agreement as well as distribution of such Co-Promotion Product in the Cost & Profit/Loss Sharing Territory by Duality or its Affiliates, and “**Co-Promotion**” shall be construed accordingly. “Co-Promotion” shall not include any Medical Affairs Activities (including medical information), marketing, pricing, market access and reimbursement.
- 1.29 “**Co-Promotion Agreement**” shall have the meaning provided in Section 7.8.
- 1.30 “**Co-Promotion Costs**” shall mean the expenses incurred by either Party in performing Co-Promotion activities in accordance with the Co-Promotion Agreement, including [***].
- 1.31 “**Co-Promotion Negotiation Period**” shall have the meaning provided in Section 7.8.
- 1.32 “**Co-Promotion Option**” shall have the meaning provided in Section 7.8.
- 1.33 “**Co-Promotion Option Exercise Date**” shall have the meaning provided in Section 7.8.
- 1.34 “**Co-Promotion Option Exercise Notice**” shall have the meaning provided in Section 7.8.
- 1.35 “**Co-Promotion Option Period**” shall have the meaning provided in Section 7.8.
- 1.36 “**Co-Promotion Plan**” shall have the meaning provided in Section 7.8.
- 1.37 “**Co-Promotion Product**” shall have the meaning provided in Section 7.8.
- 1.38 “**Co-Promotion Terms**” shall mean those terms set out in **Schedule 1.38**.
- 1.39 “**Combination Product**” shall mean [***].
- 1.40 “**Commercialization**” shall mean, with respect to a product, any and all activities undertaken before and after obtaining Regulatory Approvals relating specifically to the pre-launch, launch, promotion, detailing, marketing, pricing, reimbursement, sale, importing, exporting or transporting such product, and distribution of such product, including strategic marketing, sales force detailing, advertising, market product support, all customer support, product distribution, and invoicing and sales activities, but excluding Development and Manufacturing. “**Commercialize**”, “**Commercialized**” and “**Commercializing**” shall have the correlative meanings.
- 1.41 “**Commercialization Plan**” shall have the meaning provided in Section 7.2.
- 1.42 “**Commercially Reasonable Efforts**” shall mean, [***].
- 1.43 “**Committee**” shall have the meaning given in Section 3.3.
- 1.44 “**Competing Product**” shall mean, [***].
- 1.45 “**Competitive Change of Control**” shall mean a Change of Control of Duality where the incoming Third Party and/or its Affiliates is a Competitor.

1.46 “**Competitor**” shall mean [***].

1.47 “**Confidential Information**” shall mean all Know-How and other proprietary scientific, technical, clinical, marketing, financial or commercial information or Data Controlled by a Party or its Affiliates, which one Party or any of its Affiliates has furnished or made available to the other Party or its Affiliates, whether in oral, written or electronic form. The existence and terms of this Agreement shall be deemed Confidential Information of each Party.

1.48 “**Control**” (including any variations such as “**Controlled**” and “**Controlling**”) shall mean, with respect to any Know-How, Patents or other intellectual property rights, possession by a Party or Third Party of the right, power and authority (whether by ownership, license, sublicense or otherwise, other than by virtue of any rights granted under this Agreement) to grant access to, to grant use of, or to grant a license or a sublicense to such Know-How, Patents or intellectual property rights without violating the terms of any agreement or other arrangement with any Third Party. Notwithstanding anything in this Agreement to the contrary, a Party and its Affiliates will be deemed to not Control any Know-How, Patents, or other intellectual property rights that are in-licensed or acquired by such Party or its Affiliates from a Third Party after the Effective Date, unless the other Party agrees to (a) comply with the terms and conditions of the agreement under which such Know-How, Patents, or other intellectual property rights were in-licensed or acquired by such Party; and (b) pay all amounts that such Party would be obligated to pay in connection with the grant, maintenance and exercise of a (sub)license as reasonably allocable to such other Party for use in its territory under such Know-How, Patents, or other intellectual property rights.

1.49 “**Cost & Profit/Loss Sharing Agreement**” shall have the meaning provided in Section 2.6(d).

1.50 “**Cost & Profit/Loss Sharing Option**” shall have the meaning provided in Section 2.6(a).

1.51 “**Cost & Profit/Loss Sharing Option Exercise Notice**” shall have the meaning provided in Section 2.6(c).

1.52 “**Cost & Profit/Loss Sharing Option Exercise Date**” shall have the meaning provided in Section 2.6(c).

1.53 “**Cost & Profit/Loss Sharing Option Period**” shall have the meaning provided in Section 2.6(a).

1.54 “**Cost & Profit/Loss Sharing Territory**” shall mean the United States.

1.55 “**Cover**” shall mean, [***].

1.56 “**CRO**” shall mean a contract research organization.

1.57 “**Data**” shall mean all data, including non-clinical data, preclinical data and clinical data, including pharmacological, biological, chemical, toxicological, clinical test, safety, clinical and analytical information, quality control, trial, stability and manufacturing processes and techniques data generated by or on behalf of a Party or its Affiliates or their respective Sublicensees (in case of Licensee) and (sub)licensees and other (sub)contractors (in the case of Duality) pursuant to activities conducted under this Agreement.

1.58 [***]

1.59 “**Detail**” shall mean [***] and “**Detailing**” shall be construed accordingly. When used as a verb, “**Detail**” shall mean to engage in a Detail. [***]

1.60 “**Development**” shall mean, with respect to a pharmaceutical or biological product, any research activities, all non-clinical and clinical drug development activities and processes, [***], regulatory affairs and other activities, in each case, which are reasonably necessary to prepare submissions for, and obtain or maintain, Regulatory Approval of such product and interacting with Regulatory Authorities regarding the foregoing, including lifecycle management studies and other activities. “**Develop**”, “**Developed**”, and “**Developing**” shall have the correlative meanings.

1.61 “**Development Budget**” shall have the meaning as set forth in Section 1.64.

1.62 “**Development Costs**” shall mean [***].

1.63 “**Development Phase**” shall mean the period from the Effective Date to the First Commercial Sale of the first Original ADC Licensed Product during which either Party is conducting any Development activities for an Original ADC Licensed Product or Licensed Compound.

1.64 “**Development Plan**” shall mean a written plan approved by the JSC, and amended from time to time in accordance with the terms of this Agreement, describing [***]. The initial Development Plan, unless otherwise agreed on by the Parties, will be agreed by the Parties latest within [***] of the Effective Date.

1.65 “**Divestiture**” shall mean [***].

1.66 “**Disclosing Party**” shall have the meaning provided in Section 10.1.

1.67 “**Disclosure Schedule**” shall have the meaning provided in Section 11.2.

1.68 “**Dispute**” shall have the meaning provided in Section 15.2.

1.69 “**Duality Background IP**” shall have the meaning provided in Section 12.1(a).

1.70 “**Duality Costs**” shall mean any and all costs and expenses that are reasonably incurred by or on behalf of Duality and its applicable Affiliates after the Effective Date in conducting the Planned Trials and/or performing other Development activities as agreed hereunder in the Territory pursuant to this Agreement and the Development Plan. [***]

1.71 “**Duality CMO**” shall mean any CMO engaged by Duality or any Affiliate of Duality.

1.72 “**Duality Competing Product**” shall mean, [***].

1.73 “**Duality Development Activities**” shall have the meaning provided in Section 4.6(a).

1.74 [***] shall have the meaning provided in Section 2.10.

1.75 “**Duality In-Licensed Agreements**” shall mean each Agreement as set forth on Schedule 1.75.

1.76 “**Duality In-Licensed IP**” shall mean any and all Patents or Know-How that is Controlled by Duality or any of its Affiliates pursuant to the Duality In-Licensed Agreements.

1.77 “**Duality Indemnitees**” shall have the meaning provided in Section 14.1.

1.78 “**Duality Know-How**” shall mean any and all Know-How (including Data) that (a) is Controlled by Duality or any of its Affiliates as of the Effective Date or at any time during the Term, and (b) are necessary or reasonably useful for the Development, Manufacture or Commercialization of or to otherwise exploit the Licensed Compound or ADC Licensed Products in the Field in the Territory, including but not limited to, with respect to (a) and (b), the Know-How (including Data) contained in Duality Solely Owned Collaboration IP, [***]. Notwithstanding the foregoing, Duality Know-How shall not include (i) any Know-How (including Data) Controlled by any Third Party that becomes an Affiliate of Duality after the Effective Date as a result of a merger, acquisition or other similar transaction, unless such Know-How (including Data) is used by either Party in the Development, Manufacturing or Commercialization of the Licensed Compound or ADC Licensed Products, and (ii) any Know-How that is related to any Additional Active or other proprietary compound or product Controlled by Duality or any of its Affiliates. A description of Duality Know-How as of the Effective Date is attached hereto on **Schedule 1.78**.

1.79 “**Duality Licensed IP**” shall mean Duality Know-How and Duality Patents. Duality Licensed IP includes Duality In-Licensed IP.

1.80 “**Duality Linker-Payload**” shall mean [***].

1.81 “[***]” shall mean any new or useful invention, discovery, adaptation, redesign, modification, improvement, enhancement, contribution or other desirable change generated in the course of performing activities under this Agreement solely relating to [***]. [***]

1.82 [***]

1.83 “**Duality Linker-Payload Patents**” shall mean any and all Patents claiming the Duality Linker-Payload.

1.84 “**Duality Patents**” shall mean any and all Patents that [***].

1.85 “**Duality Product Patents**” shall mean [***].

1.86 “**Duality Solely Owned Collaboration IP**” shall have the meaning provided in Section 12.1(b).

1.87 “**Duality Solely Owned Collaboration Patents**” shall have the meaning provided in Section 12.1(b).

1.88 “**Effective Date**” shall have the meaning provided in the introductory paragraph of this Agreement.

1.89 “**Election Notice**” shall have the meaning provided in Section 2.15.

1.90 “**EMA**” shall mean shall mean the European Medicines Agency and any successor entity thereto.

1.91 “**Executive Officers**” shall have the meaning provided in Section 3.5(a).

- 1.92 “[***]” shall mean [***].
- 1.93 “[***] **Data Package**” shall have the meaning provided in Section 2.9(b).
- 1.94 “[***] **Data Package Review Period**” shall have the meaning provided in Section 2.9(b).
- 1.95 “[***] **Option**” shall have the meaning provided in Section 2.9(a).
- 1.96 “[***] **Option Exercise Notice**” shall have the meaning provided in Section 2.9(b).
- 1.97 “[***] **Option Period**” shall have the meaning provided in Section 2.9(b).
- 1.98 “**Experts**” shall have the meaning provided in Section 15.1.
- 1.99 “**FDA**” shall mean the U.S. Food and Drug Administration and any successor entity thereto.
- 1.100 “**Field**” shall mean all uses.
- 1.101 “**First Commercial Sale**” shall mean, with respect to an ADC Licensed Product, [***].
- 1.102 “**First Dosing**” shall mean, with respect to a Clinical Trial, or any portion thereof, dosing of the first human subject in such Clinical Trial or such portion thereof.
- 1.103 “**Force Majeure Event**” shall have the meaning provided in Section 16.11.
- 1.104 “**FTE**” shall mean full time equivalent.
- 1.105 “**Fully Burdened Manufacturing Cost**” shall mean, with respect to any Original ADC Licensed Product supplied by or on behalf of Duality: [***].
- 1.106 “**GCP**” shall mean any and all applicable laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the ethical conduct of Clinical Trials, including without limitation the U.S. Code of Federal Regulations (CFR) Title 21, ICH GCP Guidelines E6(R2) as amended from time to time, national legislation implementing European Community Directive 2001/20/EC (if and as still applicable), European Community Directive 2005/28/EC, and, following the applicable transition periods, the Clinical Trial Regulation (EU) No. 536/2014 (the “CTR”) and the rules, regulations and guidelines applying in the context of the CTR, and the equivalent in other countries or regions.
- 1.107 “**GCLP**” shall mean any and all applicable laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the treatment of human laboratory samples from Clinical Trials, including the relevant principles from GCP and the EMA’s reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples, as amended from time to time.
- 1.108 “**Global Trial**” shall mean a Clinical Trial designed to obtain Regulatory Approvals for an ADC Licensed Product in multiple countries through the conduct of a Clinical Trial in multiple countries, regions and/or medical institutions and conducted as part of one (1) unified Clinical Trial or separately but concurrently in accordance with a common Clinical Trial protocol.

1.109 “**GLP**” shall mean any and all applicable laws, rules, regulations, guidelines and generally accepted standards and requirements regarding quality control for laboratories to ensure the consistency and reliability of results, including without limitation the CFR Title 21, national legislation implementing European Community Directives 2004/9/EC and 2004/10/EC as amended, and the OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, and the equivalent in other countries or regions. For the purposes of this Agreement, GLP also includes the principles of Good Clinical Laboratory Practice and applicable guidelines promulgated under the ICH guidelines.

1.110 “**GMP**” shall mean any and all applicable laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the quality control and manufacturing of pharmaceutical products, including without limitation the CFR Title 21, Parts 11, 210, 211, 600 and 610, applicable ICH Guidelines including without limitation Q7 for “Active Pharmaceutical Ingredients”, national legislation implementing European Community Directive 2001/83/EC and Commission Directive 2003/94/EC as amended, EudraLex – Volume 4 of the Rules Governing Medicinal Products in the European Union including annexes, the CTR, Commission Delegated Regulation 2017/1569, the Detailed Commission Guideline (2017) 8179, and the equivalent in other countries or regions.

1.111 “**Governmental Authority**” is to be broadly interpreted and includes any multi-national or public international organization or authority, national, federal, state, local, municipal, provincial, foreign government or other governmental authority of any nature (including any governmental division, prefecture, branch, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal, or body entitled to exercise any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power, and any Regulatory Authority).

1.112 “**GXP**” shall mean collectively, all relevant and applicable good practice quality guidelines and regulations, encompassing such internationally recognized standards as GMP, GCP, GLP and GCLP, Good Distribution Practice (GDP), Good Pharmacovigilance Practice, Good Pharmacoepidemiology Practice and Good Review Practice.

1.113 “[***] **Agreement**” shall mean [***].

1.114 “**HKIAC**” shall have the meaning given in Section 15.2.

1.115 “**ICH**” shall mean the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use.

1.116 [***]

1.117 “**IND**” shall mean an investigational new drug application, clinical study application, Clinical Trial exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

1.118 “**IND Data Package**” shall have the meaning provided in Section 2.10.

1.119 “**Indemnitee**” shall have the meaning provided in Section 14.3.

1.120 “**Indemnitor**” shall have the meaning provided in Section 14.3.

1.121 “**Indication**” shall mean, [***].

- 1.122 “**Info Package**” shall have the meaning provided in Section 2.6(b).
- 1.123 “**Initiation**” shall mean, with respect to a Clinical Trial, the date upon which the first patient is dosed in such Clinical Trial.
- 1.124 “**JDC**” shall have the meaning provided in Section 3.2(b).
- 1.125 “**JIPC**” shall have the meaning provided in Section 3.2(a).
- 1.126 “[***]” shall have the meaning provided in Section 12.1(d).
- 1.127 “[***]” shall have the meaning provided in Section 12.1(d).
- 1.128 “**JSC**” shall mean the joint steering committee to be established by the Parties pursuant to Section 3.1.
- 1.129 “**Know-How**” shall mean any and all technical, scientific, regulatory and other information, trade secrets, results, knowledge, techniques, materials (including cell lines) and data, in whatever form and whether or not confidential, proprietary, whether or not patentable, invention disclosures, plans, inventions, assays, designs, protocols, and formulas, processes, practices, methods, knowledge, know how, skill, experience, ideas, concepts, test data (including pharmacological, toxicological and clinical test data), analytical and quality control data, formulae, specifications, marketing, pricing, distribution, cost, sales, and manufacturing data or descriptions. “Know-How” includes any rights including copyright, database or design rights protecting such Know-How. For clarity, Know-How does not include issued Patents, published patent application or the inventions claimed thereby.
- 1.130 “**License Payments**” shall have the meaning provided in Section 9.3(b).
- 1.131 “**Licensed Compound**” shall mean the ADC developed by or on behalf of Duality and known as DB-1311, the structure of which, is delivered to Licensee on or before the Effective Date.
- 1.132 “**Licensed Product**” shall mean any ADC Licensed Product and Sequence Licensed Product.
- 1.133 “**Licensee Added Trials**” shall have the meaning provided in Section 4.3.
- 1.134 “**Licensee Background IP**” shall have the meaning provided in Section 12.1(a).
- 1.135 “**Licensee Competing Product**” shall mean, [***].
- 1.136 [***] shall have the meaning provided in **Schedule 1.7**.
- 1.137 [***]
- 1.138 “**Licensee Indemnitees**” shall have the meaning provided in Section 14.2.
- 1.139 “**Licensee Know-How**” shall mean any and all Know-How that is Controlled by Licensee or any of its Affiliates and that is comprised by the Licensee’s Solely Owned Collaboration IP. Notwithstanding the foregoing, Licensee Know-How shall not include (i) any Know-How Controlled by any Third Party that becomes an Affiliate of Licensee after the Effective Date as a result of a merger, acquisition or other similar transaction, unless such Know-How is used by Licensee in the Development, Manufacture or Commercialization of the Licensed

Compound or Original ADC Licensed Products, and (ii) any Know-How that is related to any Additional Active or other proprietary compound or product Controlled by Licensee.

1.140 “**Licensee Licensed IP**” shall mean the Licensee Know-How and Licensee Patents.

1.141 [***]

1.142 “**Licensee Patents**” shall mean any and all Patents that are Controlled by Licensee or any of its Affiliates and that are comprised by the Licensee Solely Owned Collaboration Patents. Notwithstanding the foregoing, Licensee Patents shall not include (i) any Patent Controlled by any Third Party that becomes an Affiliate of Licensee after the Effective Date as a result of a merger, acquisition or other similar transaction, and (ii) any Patent that Covers any Additional Active or other proprietary compound or product Controlled by Licensee provided that such Patent does not Cover the Licensed Compound or Original ADC Licensed Product.

1.143 “**Licensee Solely Owned Collaboration IP**” shall have the meaning provided in Section 12.1(b).

1.144 “**Licensee Solely Owned Collaboration Patents**” shall have the meaning provided in Section 12.1(b).

1.145 “**Losses**” shall have the meaning provided in Section 14.1.

1.146 “**MAA**” shall mean an application to a Regulatory Authority for the authorization to place a product on the market in the applicable country, region or a regulatory jurisdiction, including New Drug Application and Biologics License Application, and shall include all amendments and supplements thereto, filed with the applicable Regulatory Authority to gain authorization to place such product on the market in the applicable jurisdiction.

1.147 “**MAH**” shall mean the holder of the Marketing Authorization.

1.148 “**Mainland China**” shall mean the mainland of the People’s Republic of China.

1.149 “**Major [***] Market**” shall mean [***] for the purpose of this Agreement.

1.150 “**Manufacture**” shall mean, with respect to a Licensed Product, activities related to the manufacture and supply of such Licensed Product, including manufacturing supplies for Development or Commercialization, packaging, labeling, in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance and quality control activities related to manufacturing and release of product, ongoing stability tests, storage, and shipment and regulatory activities directly related to any of the foregoing, but not including any Development or Commercialization activities. “**Manufactured**” and “**Manufacturing**” shall have the correlative meanings.

1.151 “**Manufacturing IP**” shall mean any Patents and Know-How that (i) are generated, developed or conceived during the course of performing activities under this Agreement depending on Duality Licensed IP, and (ii) specifically related to, and (iii) are necessary for the Manufacture of the Duality Linker-Payload; notwithstanding the foregoing, Manufacturing IP shall exclude Licensee Background IP.

1.152 “**Marketing Authorization**” shall mean the authorization by all relevant Regulatory Authorities of an MAA in a given country or regulatory region/jurisdiction and the granting of the required authorization for the sale of a product which will include any Pricing and

Reimbursement Approvals if required by Applicable Law of the respective country to initiate marketing and selling of a product in such particular country.

1.153 “**MCB**” shall mean the master cell bank.

1.154 “**Medical Affairs Activities**” shall mean the coordination of medical information requests and field based medical scientific liaisons with respect to an Original ADC Licensed Product, including activities of medical scientific liaisons, activities involving key opinion leaders, and the provision of medical information services with respect to an Original ADC Licensed Product.

1.155 “**Multi-Specific ADC Product**” shall mean [***].

1.156 “**Negotiation Period**” shall have the meaning set forth in Section 2.15.

1.157 “**Net Sales**” shall mean, [***]

[***]

1.158 “**Non-Arbitral Subject Matter**” shall have the meaning given in Section 15.3.

1.159 “**Offer Notice**” shall have the meaning given in Section 2.15.

1.160 “**Original ADC Licensed Product**” shall mean [***].

1.161 “**Other ADC Licensed Products**” shall mean [***] and [***].

1.162 “[***]” shall have the meaning given in Section 8.8(b)(ii).

1.163 “**Party**” shall mean Licensee or Duality individually, and “**Parties**” shall mean Licensee and Duality collectively.

1.164 “**Patents**” shall mean (a) patent applications filed in the applicable jurisdiction; (b) all patents, including supplemental protection certificates, that have issued or in the future issue from any of the foregoing, including utility models, design patents and certificates of invention; and (c) all divisionals, continuations, continuations-in-part, reissues, re-examination certificates, renewals, extensions or additions to any such patents and patent applications (as applicable).

1.165 “**Pharmacovigilance Agreement**” shall have the meaning provided in Section 5.7.

1.166 “**Phase I Clinical Trial**” shall mean a human clinical trial of a product, the principal purpose of which explores the optimal dose and is a determination of initial tolerance or safety of such product in healthy volunteers or the target patient population, as described in 21 CFR 312.21(a) (as amended or any replacement thereof), or a similar clinical trial prescribed by the Regulatory Authority in a country other than the United States.

1.167 “**Phase II Clinical Trial**” shall mean a human clinical trial of a product, the principal purpose of which is a determination of safety and efficacy in the target patient population, (i.e. “proof of concept”), as described in 21 C.F.R. 312.21(b) (as amended or any replacement thereof), or a similar clinical trial prescribed by the Regulatory Authority in a country other than the United States.

1.168 “Phase III Clinical Trial” shall mean a human clinical trial of a product, the design of which is acknowledged by the FDA to be sufficient for such clinical trial to satisfy the requirements of 21 C.F.R. 312.21(c) (as amended or any replacement thereof), or a similar human clinical trial prescribed by the Regulatory Authority in a country other than the United States, the design of which is acknowledged by such Regulatory Authority to be sufficient for such clinical trial to satisfy the requirements of a pivotal efficacy and safety clinical trial.

1.169 “PhRMA” shall mean the Pharmaceutical Research and Manufacturers of America.

1.170 “Planned Trials” shall have the meaning given in Section 4.3.

1.171 “Pricing and Reimbursement Approval” shall mean, in any country where a Regulatory Authority authorizes reimbursement for, or approves or determines pricing or level of reimbursement for, pharmaceutical products, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization and/or pricing approval or determination (as the case may be).

1.172 “Product Marks” shall have the meaning provided in Section 7.5.

1.173 “Project Manager” shall have the meaning provided in Section 3.9.

1.174 “Proposed Publication” shall have the meaning provided in Section 10.5(a).

1.175 “Publication” shall have the meaning provided in Section 10.5.

1.176 [*]**

1.177 “Receiving Party” shall have the meaning provided in Section 10.1.

1.178 “[*]”** shall mean the reduced royalty rates for the [***] and [***] specified in the second table in Section 8.5.

1.179 “Registrational Trial” shall mean, with respect to a product, a human clinical trial (regardless of whether such clinical trial is referred to as a “Phase II Clinical Trial”, “Phase IIb Clinical Trial”, “Phase II/III Clinical Trial”, “Phase IIb/III Clinical Trial” or “Phase III Clinical Trial”) for such product, the results of which, together with prior information concerning such product, are determined by the sponsor to be intended to be sufficient to establish that such product is safe and effective for its intended Indication to support the filing of an MAA. [***]

1.180 “Regulatory Approval” shall mean any and all approvals, licenses, permits, registrations or authorizations of or from any Regulatory Authority that are necessary to market (including Marketing Authorization) and sell a pharmaceutical product in any country, region or other jurisdiction. For clarity, unless it is required by the Applicable Law to initiate marketing and selling of a product in a particular country, Regulatory Approval shall not include Pricing and Reimbursement Approval.

1.181 “Regulatory Authority” shall mean with respect to a country, any national, federal, supranational, state or local regulatory agency, council, department, bureau or other governmental or regulatory authority having the administrative authority to regulate the development or marketing of pharmaceutical products in any country, region or jurisdiction. including the Regulatory Approvals.

1.182 [*]**

1.183 “**Regulatory Materials**” shall mean, with respect to a product, regulatory applications (including MAA) and all applications, filings, submissions, notifications, materials, communications, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority in order to Develop, Manufacture, market, sell or otherwise Commercialize such product in a particular country, region or jurisdiction.

1.184 “**Remedial Action**” shall have the meaning provided in Section 5.8.

1.185 “**Retained Territory**” shall mean Mainland China, Hong Kong Special Administrative Region, and Macau Special Administrative Region.

1.186 “**Review Period**” shall have the meaning provided in Section 10.5(a).

1.187 “[***]” shall have the meaning provided in Section 2.15.

1.188 “[***]” shall have the meaning provided in Section 8.7(d).

1.189 “**Royalty Term**” shall have the meaning provided in Section 8.6.

1.190 “**Rules**” shall have the meaning provided in Section 15.1.

1.191 “**SSC**” shall mean the Sales Steering Committee for the Co-Promotion Products.

1.192 “**SEC**” shall have the meaning provided in Section 10.4(a)(i).

1.193 “**Selling Party**” shall have the meaning as provided in Section 1.157.

1.194 “**Separate**” shall mean, [***].

1.195 “[***]” shall mean [***].

1.196 “[***]” shall mean any Patents and Know-How relating to the Sequence Licensed Product created, conceived, discovered, developed, reduced to practice, invented or otherwise generated in the course of performance of activities under this Agreement. Sequence Licensed Product IP [***].

1.197 “[***] **Dosing**” shall mean, with respect to a Clinical Trial, or any portion thereof, dosing of the [***] in such Clinical Trial or such portion thereof.

1.198 “**Solely Owned Collaboration IP**” shall mean Duality Solely Owned Collaboration IP and Licensee Solely Owned Collaboration IP, as applicable.

1.199 “**Solely Owned Collaboration Patents**” shall mean Duality Solely Owned Collaboration Patents and Licensee Solely Owned Collaboration Patents, as applicable.

1.200 “**Sublicense**” shall mean a license, sublicense, covenant not to sue or other rights granted by Licensee to a Third Party under the rights it receives from Duality in accordance with Section 2.2, to Develop, Manufacture, Commercialize or otherwise exploit a Licensed Compound or a Licensed Product, but excluding any grant of rights to or agreement with (a) any Third Party acting as a service provider or subcontractor for such Party or its Affiliates, or (b) any Third Party wholesaler, distributor, or the like.

1.201 “**Sublicensee**” shall mean a Third Party that is receiving rights under a Sublicense.

- 1.202 “**Successful Completion**” shall mean, [***].
- 1.203 “**Target**” shall mean, with regard to an Antibody or ADC and a biological target in question, that such Antibody or ADC demonstrates meaningful binding activity to such biological target and “**Targeting**” shall be construed accordingly.
- 1.204 “**Tax Withholdings**” shall have the meaning provided in Section 9.3(b).
- 1.205 “**Term**” shall have the meaning provided in Section 13.1.
- 1.206 “**Territory**” shall mean worldwide except the Retained Territory. For clarity, Territory **shall include Taiwan**.
- 1.207 “**Third Party**” shall mean any entity other than Licensee and its Affiliates and Duality and its Affiliates.
- 1.208 “**Third Party Agreements**” shall have the meaning provided in Section 4.6(c).
- 1.209 “**Third Party Claims**” shall have the meaning provided in Section 14.1.
- 1.210 “**UNCITRAL**” shall have the meaning given in Section 15.2.
- 1.211 “**United States**” or “**U.S.**” shall mean the United States of America, including its territories and possessions as recognized by the United Nations from time to time, but in all cases including, for clarity, Puerto Rico.
- 1.212 “**US\$**” or “**U.S. Dollars**” shall mean U.S. dollars, the lawful currency of the U.S.
- 1.213 “**Updated Disclosure Schedule**” shall have the meaning provided in Section 11.8.
- 1.214 “**Upfront Payment**” shall have the meaning provided in Section 8.1.
- 1.215 “**Valid Claim**” shall mean [***].
- 1.216 “**Wind-Down or Transfer Plan**” shall mean a plan for the wind-down or transfer of any ongoing Development, Manufacture and Commercialization (if any) activities of Licensee with respect to the Licensed Products for which the license grant in Section 2.1 has been terminated and the transfer of relevant Licensed Products, as applicable.
- 1.217 “[***] **Agreements**” shall mean both the [***] License Agreement and the [***].
- 1.218 “[***] **License Agreement**” shall mean [***].
- 1.219 “[***] **In-Licensed IP**” shall mean any and all Patents and Know-How that is exclusively granted to Duality or any of its Affiliates pursuant to the [***] License Agreement.
- 1.220 “[***]” shall mean [***].
- 1.221 “[***]” shall mean [***].
- 1.222 “[***]” shall mean [***].
- 1.223 “**WCB**” shall mean the working cell bank.

ARTICLE 2 LICENSE

2.1 License Grant.

(a) **Territory License Grant.** Subject to the terms and conditions of this Agreement (including Duality's retained rights in Section 2.4), Duality hereby grants and shall procure its Affiliates grant to Licensee and its Affiliates, during the Term, an exclusive (even as to Duality and its Affiliates), royalty-bearing license, with the right to sublicense through multiple tiers (in accordance with Section 2.2), under (i) Duality Licensed IP to Develop, have Developed, Manufacture, have Manufactured use, sell, offer for sale, import and otherwise Commercialize or have Commercialized or exploit the ADC Licensed Products in the Field in the Territory, and (ii) [***] In-Licensed IP to Develop, have Developed, Manufacture, have Manufactured, use, sell, offer for sale, import and otherwise Commercialize, have Commercialized or exploit the Sequence Licensed Products in the Field in the Territory.

(b) **Retained Territory License Grant.** Subject to the terms and conditions of this Agreement (including Duality's retained rights in Section 2.4), Duality hereby grants to Licensee a sole license under (i) Duality Licensed IP to Develop, have Developed, Manufacture or have Manufactured the Licensed Compound and the ADC Licensed Products in the Retained Territory solely for the purpose of Developing, Manufacturing and Commercializing the ADC Licensed Products in the Field in the Territory and (ii) [***] In-Licensed IP to Develop, Manufacture or have Manufactured the [***] Licensed Products in the Retained Territory solely for the purpose of Developing, Manufacturing and Commercializing the Sequence Licensed Products in the Field in the Territory.

(c) **Covenant not to sue.** Subject to the terms and conditions of this Agreement, [***].

2.2 Sublicense Rights.

(a) **Right to Sublicense.** Subject to the terms and conditions of this Agreement, Licensee and its Affiliates shall have the right to grant Sublicenses through multiple tiers under Duality Licensed IP (including Duality In-Licensed IP), in each respect to (i) any Affiliate, or (ii) to any Third Party.

(b) **Sublicense Terms.** [***]

(c) **Licensee's Responsibility.** Licensee shall use Commercially Reasonable Efforts to ensure that the performance by any of its Affiliates, Sublicensees and subcontractors hereunder is in accordance with the applicable terms of this Agreement. With respect to a patent challenge by the Sublicensee against any Duality Patents, if Licensee fails to cause such Sublicensee to cease such violation within a reasonable period of time, Licensee shall, in so far as it is not prohibited under the Applicable Laws, terminate the sublicense agreement.

2.3 Negative Covenants. In so far as it is not prohibited under the Applicable Laws, Licensee hereby covenants on a country-by-country basis not to, and not to permit or cause any Affiliate to [***]. Notwithstanding the foregoing, this Section shall in no way restrict [***], its Affiliates, its Sublicensees or their CMOs and other authorized Third Party under this Agreement

from undertaking any research, Development, Manufacturing, Commercialization, or other exploitation or engaging in any activities involving [***] that anyone not subject to this Agreement may legally undertake before the Effective Date and during the Term in the Territory and elsewhere, [***]. [***]

2.4 No Implied Licenses; Retained Rights. No right or license under any Patents or Know-How of either Party is granted or shall be granted by implication. All such rights or licenses are or shall be granted only as expressly provided in the terms of this Agreement. Duality hereby expressly reserves all rights not expressly licensed to Licensee in Section 2.1, including (i) all rights under the Duality Licensed IP with respect to the Licensed Compound and Original ADC Licensed Products in the Retained Territory, subject to Licensee's co-exclusive license as set forth in Section 2.1(b), (ii) all rights under the Duality Licensed IP to exercise its rights or perform its obligations under this Agreement, and (iii) all rights under the Duality Licensed IP to conduct Development activities in the Territory for the sole purpose of Developing or Commercializing the Original ADC Licensed Products in the Field in the Retained Territory; *provided that* any such Development activities in the Territory in relation to the Original ADC Licensed Product and Licensed Compound shall be undertaken for Duality by Licensee or its Affiliates, or Sublicensees or Licensee's designated subcontractors.

2.5 License to Duality. Licensee hereby grants to Duality a non-exclusive, non-transferrable, non-sublicensable (unless a sublicense was consented to by Licensee in writing and is in compliance with the license terms set out in Section 2.2(b), which would apply *mutatis mutandis*), royalty-free license under the Licensee Licensed IP, during the Term of this Agreement, solely to (i) perform, either itself, through its Affiliates, or through subcontractors, its obligations under this Agreement, including its Manufacturing and supply obligations under Sections 6.1, 6.4 and 6.5, and (ii) limited to the Field and the Retained Territory, to Develop, Manufacture or have Manufactured, or Commercialize the Licensed Compound or Original ADC Licensed Products. Duality shall use Commercially Reasonable Efforts to ensure that the performance by any of its Affiliates or subcontractors hereunder is in accordance with the applicable terms of this Agreement. With respect to a patent challenge by a (sub)licensee against any Licensee Patents, if Duality fails to cause such (sub)licensee to cease such violation within a reasonable period of time, Duality shall, in so far as it is not prohibited under the Applicable Laws, terminate such (sub)license agreement. Duality shall be responsible for any actions of its Affiliates and subcontractors who act on behalf of Duality to perform activities assigned to Duality (for or on behalf of Licensee) pursuant to this Agreement, to the same extent as if such actions had been taken by Duality itself, and Licensee shall have the right to proceed directly against Duality without any obligation to first proceed against such Affiliate, sublicensee and subcontractor.

2.6 Cost & Profit/Loss Sharing Option.

(a) In partial consideration of the licenses granted to Licensee under this Agreement and the performance of the Duality Development Activities, Licensee hereby grants to Duality an exclusive option to share the Development and Commercialization costs and the profits and losses from the exploitation of the first Original ADC Licensed Product in the Cost & Profit/Loss Sharing Territory [***] in accordance with this Section 2.6 and Section 8.8 below ("**Cost & Profit/Loss Sharing Option**"), which option may be exercised by Duality at any time during the period commencing from [***] (the "**Cost & Profit/Loss Sharing Option Period**"). [***]

(b) Within [***] days after [***], Licensee shall provide Duality with a package containing the following information [***]. For clarity, this Section 2.6 (b) shall only apply to [***]. The information package referred to in this Section 2.6 (b) hereinafter referred to as the ("**Info Package**").

(c) Prior to the expiration of the Cost & Profit/Loss Sharing Option Period, Duality shall notify Licensee in writing of its desire to exercise the Cost & Profit/Loss Sharing Option (the “**Cost & Profit/Loss Sharing Option Exercise Notice**”, such date of the Cost & Profit/Loss Sharing Option Exercise Notice, the “**Cost & Profit/Loss Sharing Option Exercise Date**”). [***]

(d) [***]

(e) [***]

2.7 Know-How Transfer.

Within [***] days of the Effective Date, Duality shall, at its cost and expense, provide to Licensee [***] the documents embodying all Duality Know-How (including CMC documentation to the extent available to Duality or any of its Affiliates as of the Effective Date) Controlled by Duality or any of its Affiliates as of the Effective Date, including but not limited to [***] A description of such documents for the initial Know-How Transfer as of the Effective Date is attached as **Schedule 2.7** hereto. Thereafter, Duality shall promptly (and in any event no later than [***] from the existence of such Know-How) inform Licensee of the existence of any additional Duality Know-How that becomes Controlled by Duality after the Effective Date and during the Term. The Parties shall discuss the timing and means of the transfer of additional Duality Know-How and Duality shall provide, and shall cause Third Parties to provide (as applicable), electronic copies of such additional Duality Know-How to Licensee in accordance with Licensee’s request, in a manner in line with that for the initial Know-How transfer and at no additional cost to Licensee.

2.8 Non-Competition.

[***]

2.9 [***]

2.10 [***]

2.11 [***]

2.12 [***]

2.13 [***]

2.14 [***] **Agreements and Third Party Agreements.**

(a) The licenses and other rights granted to Licensee under this Agreement (including [***]).

(b) [***].

2.15 [***]

ARTICLE 3 GOVERNANCE

3.1 Joint Steering Committee. Within [***] days following the Effective Date, the Parties shall establish a JSC comprised of an equal number of representatives from each Party to approve, plan, coordinate, integrate monitor and oversee the Development, Manufacture, regulatory and Commercialization (solely in the Cost & Profit/Loss Sharing Territory after the Cost & Profit/Loss Sharing Option Exercise Date) activities of the Parties' in the Territory with respect to the Original ADC Licensed Product and facilitate information exchange between the Parties under this Agreement. The JSC, as may be conducted through the applicable Subcommittee, shall in particular:

- (a) review, discuss and coordinate the overall strategy for the Development of the Original ADC Licensed Products in the Territory;
- (b) review, discuss and approve any proposed amendments or revisions to the Development Plan(s) of the Original ADC Licensed Products, including all related budgets of the Development activities;
- (c) review, discuss and approve any study protocols relating to the Development Plan(s) (and any amendments thereto) of the Original ADC Licensed Products;
- (d) review, discuss and serve as a forum for the sharing of information between the Parties regarding the operation of any Development activities of the Original ADC Licensed Products in the Territory and in the Retained Territory;
- (e) after the exercise of Cost & Profit/Loss Sharing Option, review, discuss and serve as a forum for the sharing of information between the Parties regarding the Commercialization strategy and the Commercialization budget for the Cost & Profit/Loss Sharing Territory;
- (f) oversee and coordinate the on-going disclosure, sharing and/or transfer of new Collaboration IP generated in or related to the Development of the Original ADC Licensed Products in the Territory;
- (g) review and discuss any matters relating to the Regulatory Approvals and Regulatory Materials to be submitted to any Regulatory Authority in respect of the Original ADC Licensed Products in the Territory and matters relating to attending regulatory meetings or consultations with Regulatory Authorities in respect of the Original ADC Licensed Products in the Territory;
- (h) coordinate supply of Original ADC Licensed Products in accordance with Article 6;
- (i) review and discuss the clinical protocol of and Duality's potential participation in any Global Trial sponsored by Licensee or any of its Affiliates and Sublicensees, or Licensee Added Trials; and
- (j) perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or as determined by the Parties in writing.

3.2 Subcommittees.

From time to time during the Term, the JSC may establish and disband one or more subcommittee(s) (each, a “**Subcommittee**”) to oversee particular activities of the Parties, and the JSC may assign to such subcommittee(s) duties or tasks independent of the duties of the JSC, or delegate part of such duties of the JSC to such subcommittee(s) as it deems necessary and appropriate.

(a) **Joint IP Committee.** Without limiting the generality of the foregoing subsection (a), no later than [***] days after the Effective Date (unless otherwise agreed by the Parties), the JSC shall establish an intellectual property committee (the “**Joint IP Committee**” or “**JIPC**”) led by Licensee and comprised of an equal number of representatives from each Party. The JIPC shall provide a forum for discussion of the patenting strategies of the Original ADC Licensed Products and coordinate the Parties’ efforts in accordance with the provisions set forth in Article 12 and other matters related to the prosecution and maintenance of intellectual property rights hereunder, including submissions to and addressing notices from Regulatory Authorities that relate to regulatory-patent linkage procedures and proceedings. The JSC shall determine the desired membership of the JIPC and once formed, Licensee’s committee members shall determine the time, place and procedure of meetings. [***]

(b) **Joint Development Committee.** Without limiting the generality of the foregoing subsection (a), no later than [***] days after the Effective Date, the JSC shall establish a joint development committee (the “**Joint Development Committee**” or “**JDC**”) led by Licensee and comprised of an equal number of representatives from each Party. The JDC shall (i) oversee the implementation and progress of the Development Plan in the Territory, (ii) discuss and propose to the JSC for approval any amendments to the Development Plan, (iii) oversee any Global Trials.

3.3 Composition; Meetings. The JSC and each Subcommittee (each, a “**Committee**”) shall be composed of [***] representatives from each Party (or such other equal number of representatives of each of Licensee and Duality as the JSC may determine), and each Party shall notify the other Party of its initial JSC representatives within [***] days after the Effective Date. Each Party shall designate a representative to be the co-chairperson of the JSC and Licensee shall designate a representative to chair each Subcommittee led by it, in each case, who shall schedule meetings, prepare meeting agendas and meeting minutes and follow up on action items. Each Party may request and convene a Committee meeting and propose agenda therefor at any time. With respect to the JSC, these responsibilities will alternate between the Parties or each co-chairperson, as applicable, with Licensee’s co-chairperson taking the responsibility for the first meeting of the JSC. Each Party may change its representatives to the JSC (or any Subcommittee) from time to time in its sole discretion, effective upon notice to the other Party of such change. Each Party’s representatives in each Committee shall possess appropriate experience with respect to the issues falling within the functions of such Committee and requisite seniority within such Party’s organization, and shall have the authority to make decisions on behalf of the Party they represent.

3.4 Non-Member Attendance. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend a meeting of any Committee (in a non-voting capacity) in the event that the planned agenda for such Committee meeting would require such participants’ expertise; provided that if either Party intends to have any Third Party (including any consultant or counsel) attend such a meeting, such Party shall provide prior written notice to the other Party, shall obtain approval from such other Party for such Third Party to attend (which shall not be unreasonably withheld, conditioned or delayed by the notified Party), and shall

ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

3.5 Decision-Making. The representatives of each Party will have, collectively, [***] at each Committee on all matters brought before such Committee. The Committees may not take any action or decide any matter except at a meeting attended by [***] representing each Party and [***].

(a) **JSC Decisions.** Except where consent or approval on any matter by a Party is expressly required herein, if after reasonable discussion and good faith consideration of each Party's view on any matter within the decision-making authority of the JSC (including those matters referred to the JSC by any Subcommittee), the representatives of the Parties on the JSC cannot reach an agreement as to such matter within [***] Days after such matter was brought to the JSC for resolution or after such matter has been referred to the JSC, such disagreement shall be referred to the [***] (collectively, the "**Executive Officers**") for resolution. If the Executive Officers cannot resolve such matter within [***] days (or such other timeframe as the JSC may request in consideration of the urgency of such referred matter) after such matter has been referred to them, then:

(i) [***] shall be entitled to make final decisions with respect to:

[***]

(ii) [***]

(b) **JIPC Decisions.** Except where consent or approval on any matter by a Party is expressly required herein, if after reasonable discussion and good faith consideration of each Party's view on any matter within the decision-making authority of the JIPC, together with the assistance of each Party's outside intellectual property counsel (as required and pursuant to Section 3.4), the representatives of the Parties on the JIPC cannot reach an agreement as to such matter within [***] Days after such matter was brought to the JIPC for resolution or after such matter has been referred to the JIPC, such matter shall be escalated to the JSC by either Party.

(c) **JDC Decisions.** Except where consent or approval on any matter by a Party is expressly required herein, if after reasonable discussion and good faith consideration of each Party's view on any matter within the decision-making authority of the JDC, the representatives of the Parties on the JDC cannot reach an agreement as to such matter within [***] Days after such matter was brought to the JDC for resolution or after such matter has been referred to the JDC, such disagreement shall be escalated to the JSC by either Party.

(d) **Deadlock Resolution.** In case of a deadlock with respect to the decision-making process of the JSC, Section 15.1 shall apply.

3.6 Limitations on Authority. The JSC shall have only such powers as are expressly assigned to it in this Agreement, and such powers shall be subject to the terms and conditions of this Agreement. Without limiting the generality of the foregoing, the JSC shall not have the power to amend this Agreement, shall not have power in relation to [***], and no decision of the JSC may be in contravention of any terms and conditions of this Agreement. For clarity, the JSC shall have no decision-making authority regarding any Development, Manufacturing, Commercialization or other activity in the Retained Territory save as contemplated by Section 3.5(a) or otherwise expressly provided in this Agreement.

3.7 Meetings. The JSC will hold a meeting every [***] until the Development Phase ends, and afterwards every [***], or as otherwise determined by the JSC. Such meetings may be in person, via videoconference, or via teleconference. The location of in-person meetings will be determined by the Parties. At least [***] prior to each JSC meeting, each Party shall provide written notice to the other Party of agenda items proposed by such Party for discussion at such meeting, together with appropriate information related thereto. Reasonably detailed written minutes will be kept for all JSC meetings. Meeting minutes will be prepared [***] and sent to each member of the JSC for review and approval within [***] Days after the meeting. Minutes will be deemed approved unless a member of the JSC objects to the accuracy of such minutes within [***] Days of receipt. In the event of any such objection that is not resolved by mutual agreement of the Parties, such minutes will be amended to reflect such unresolved dispute.

3.8 Discontinuation of JSC. The JSC shall continue to exist until the Parties mutually agree to disband the JSC. Once the JSC is disbanded, the JSC shall have no further obligations under this Agreement and, thereafter, the Alliance Managers shall be the points of contact for the exchange of information under this Agreement, and the Parties shall reach decision directly on matters that are subject to the decision of the JSC as set forth in Section 3.1.

3.9 Project and Alliance Managers. Each Party shall appoint an individual, who is an employee of such Party, to act as a project manager (the “**Project Manager**”) who shall be responsible for implementing and coordinating activities and facilitating the exchange of information between the Parties. Each Party shall appoint an individual, who is an employee of such Party, to act as its alliance manager under this Agreement within [***] Days after the Effective Date (the “**Alliance Manager**”). [***] The Project Managers shall: (a) serve as the primary points of contact between the Parties for the purpose of providing the other Party with information on the progress of a Party’s activities under this Agreement; (b) be responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties. The Alliance Managers shall: (a) serve as the primary points of contact between the Parties for any issues arising under this Agreement; (b) facilitate the prompt resolution of any disputes; and (c) attend JSC and Subcommittee meetings (in each case, as a non-voting participant); provided that the Alliance Managers shall not count toward the number of representatives that each Party may have on each such Committee. An Alliance Manager may also bring any matter to the attention of the JSC, if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party may replace its Project Manager and Alliance Manager at any time upon written notice to the other Party.

ARTICLE 4 DEVELOPMENT

4.1 Overview; Diligence.

(a) Except as expressly provided herein with respect to the Planned Trials, Licensee Added Trials (as applicable), Licensee (itself and through its Affiliates and their respective Sublicensees) shall be responsible, at its own expense, for the Development of the Original ADC Licensed Products in the Field in the Territory under the oversight of JSC. Without limiting the generality of the foregoing, Licensee shall, in accordance with the Development Plan (i) use Commercially Reasonable Efforts to Develop and seek Regulatory Approval for [***] in the Field in [***], and (ii) perform the Development activities assigned to it under the Development Plan(s) and in compliance with Applicable Laws (including GXPs), with reasonable due care and in conformity with current generally accepted industry standards and procedures. Licensee shall use Commercially Reasonable Efforts to adhere to the timelines set forth in the Development Plan.

(b) Without limiting the foregoing, Licensee shall use Commercially Reasonable Efforts to (i) make all regulatory submissions to the applicable Regulatory Authorities within the Territory in respect of the Original ADC Licensed Product; and (ii) obtain Regulatory Approval for Original ADC Licensed Products in the Territory, in each case of (i) and (ii) in accordance with the Development Plan.

4.2 Development Plan. The Parties will agree on the initial Development Plan, which sets forth the scope, timelines and responsibilities of each Party of the Development activities to be conducted by or on behalf of Licensee in order to obtain Regulatory Approvals for the Original ADC Licensed Products in the Territory. [***] From time to time during the Term, either Party may propose written amendments and updates to the then-current Development Plan, and shall submit such amendments and updates to the JSC for review and approval. The amendment of the Development Plan and the Development Budget shall become effective only upon the approval of the JSC.

4.3 Clinical Trials to Be Conducted by Duality in the Territory. As of the Effective Date and as set forth in the Development Plan, the Parties have agreed that Duality will conduct, at its own cost and expense, the Clinical Trials in the Territory until [***] in accordance with the Development Plan and in compliance with all Applicable Laws (together, "**Planned Trials**"); [***].

4.4 Global Trials. [***]

4.5 Phase [*] Clinical Trial.** [***].

4.6 Duality Development Activities.

(a) Where Duality is responsible for conducting Development activities under this Agreement in the Territory, including but not limited to conducting the Planned Trials, and if applicable, [***] ("**Duality Development Activities**"), [***].

(b) Any intended delegation of the Duality Development Activities or any part thereof to a subcontractor shall be communicated to Licensee via the JDC in advance and shall be reflected in the Development Plan, already listing the subcontractors that Duality intends to involve. The delegation to a subcontractor requires Licensee's prior written consent which shall not be unreasonably withheld, conditioned or delayed; provided that Licensee shall be deemed to have given its consent if Licensee's Project Manager and Licensee's Alliance Manager, who were informed about the identity of the subcontractor via the JDC, do not respond within [***] Days after both Licensee's Project Manager's and Licensee's Alliance Manager's receipt of written notice from Duality; provided further that such notice contains sufficient information for Licensee to make an informed decision.

(c) Duality shall, upon request by Licensee, (i) keep Licensee copied on the main communications regarding the contract negotiations with the subcontractor and Licensee may decide, at its own discretion, to participate in the contract negotiations with the subcontractor; provided that Duality does not need to reschedule negotiations because of Licensee's unavailability, and (ii) provide Licensee with a copy of any draft subcontractor agreement proposed to it with respect to the Duality Development Activities ("**Third Party Agreements**"), including but not limited to agreements with CROs. Such Third Party Agreements shall be in the English language. Any such Third Party Agreement will only be signed after obtaining a written consent of Licensee which shall not be unreasonably withheld, conditioned or delayed; provided that Licensee shall be deemed to have given its consent if Licensee's Project Manager and Licensee's Alliance Manager were copied on the main communications regarding the contract negotiations, given the

opportunity to participate in the contract negotiation, and regularly updated on the progress of the negotiations (together with the draft Third Party Agreement) and do not respond within [***] Days after both Licensee's Project Manager's and Licensee's Alliance Manager's receipt of the fully copy of such draft Third Party Agreements and the written notice from Duality.

4.7 Development Records. Each Party shall maintain or cause to be maintained complete, current and accurate records of all activities conducted by or on behalf of it pursuant to the Development Plan(s), and all Know-How and other information resulting from such activities. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes. Each Party shall, and shall ensure that its Affiliates and their Sublicensees will, document all non-clinical studies and Clinical Trials in formal written study records in accordance with all Applicable Laws, including applicable national and international guidelines such as ICH, GCLP, GCP and GLP. To the extent permitted by the Applicable Laws, each Party shall have the right to review and copy such records of the other Party at reasonable times and to obtain access to review the original to the extent necessary or useful for regulatory, patent or other reasonable purposes for the purpose of fulfilling its obligations under this Agreement upon reasonable notice to such other Party and at a time and location mutually acceptable to the Parties.

4.8 Development Reports. Each Party shall keep the other Party reasonably and timely informed of the progress and results of its and its Affiliates', subcontractors' and Sublicensees'/(sublicensees' work under the Development Plan(s) (including prompt reporting of available pre-clinical and clinical data). Without limiting the generality of the foregoing, each Party shall provide the other Party with a written report no later than [***] days after the end of each Calendar Year setting forth in details the Development activities performed during such Calendar Year and the results thereof, and comparing such activities with the Development Plan(s) for such time period. Such reports prepared by each Party shall be provided at a level of detail reasonably sufficient to enable the other Party to determine the other Party's compliance with its obligations under this Agreement. At each JSC meeting, the Parties shall discuss the status, progress and results of the Development activities conducted by the Parties pursuant to this Agreement. Each Party shall promptly respond to the other Party's reasonable questions or requests for additional information relating to such Development activities. In the event that Duality is engaged by Licensee to conduct Duality Development Activities in the Territory, Duality shall send the Development report [***], setting forth in more detail the Duality Development Activities performed [***].

ARTICLE 5 REGULATORY

5.1 Overview of Conduct of Regulatory Activities.

(a) Licensee (itself and through its Affiliates and Sublicensees, as applicable) shall be responsible for all of the costs for all regulatory activities with respect to the Licensed Products in the Territory after the Effective Date. [***], Licensee (or its Affiliate or Sublicensees) shall be the sponsor and holder of all Regulatory Approvals for the Licensed Products in the Territory. For clarity, Licensee (or one of its Affiliates or their Sublicensees) shall always be the MAH of the Original ADC Licensed Products in the Territory.

(b) Following the Effective Date, Duality shall provide Licensee with one (1) electronic copy of the Regulatory Materials related to the Licensed Compound and Original ADC Licensed Products in the Territory existing and possessed by Duality as of the Effective Date. At any time during the Term, if Duality is the sponsor or holder of the Regulatory Materials and upon Licensees' written request, Duality shall provide Licensee with electronic copies of the Regulatory Materials related to the Licensed Compound or Original ADC Licensed Products in the Territory received and possessed by Duality after the Effective Date promptly and in any event no later than [***] Days after such Regulatory Materials become available.

5.2 Regulatory Filing; Ownership.

(a) **Regulatory Filings.** Except with respect to regulatory filings related to the Planned Trials and Licensee Added Trials (if any), for which Duality shall be responsible unless the Parties agree otherwise, (i) Licensee (and its Affiliates or Sublicensee, as applicable) shall lead and have sole control over preparing and submitting all regulatory filings related to the Licensed Compound and Original ADC Licensed Products, including all applications for Regulatory Approval, in the Territory at Licensee's sole cost and expense, and (ii) Duality shall be responsible for the preparation and submission of any regulatory filings in the Retained Territory at Duality's sole cost and expense. With respect to regulatory filings for the Planned Trials or and the Licensee Added Trials (if any) that are prepared by Duality, Duality shall submit all such regulatory filings to the JSC for its review and approval.

(b) **Ownership.** Other than any Regulatory Approvals or applications therefor that are related to the Planned Trials or Licensee Added Trials (if any), for which Licensee has designated Duality to be the sponsor, Licensee (or its Affiliates or Sublicensees, as applicable) shall own any and all Regulatory Approvals (and applications for Regulatory Approvals), and any other regulatory filings related to the Licensed Compound and ADC Licensed Products in the Territory, including Data and data in the regulatory filings and Regulatory Materials, which shall be held in the name of Licensee or its designees.

(c) **English Translation.** To the extent that the original language is not English, Duality shall provide Licensee with a certified full English translation of all Regulatory Materials.

5.3 Interactions with Regulatory Authorities. Insofar as it relates to the Planned Trials and Licensee Added Trials (if any) where Licensee has confirmed and consented in writing that Duality is the sponsor, Duality shall lead interactions with Regulatory Authorities in the Territory; provided that JSC shall have final decision making authority in relation to such interactions with Regulatory Authorities and Duality shall follow all instructions provided to it by the JSC in this regard and Duality shall provide Licensee with (i) access to or copies of all material written or electronic communication received by Duality or its Affiliates from any Regulatory Authorities in the Territory and in the Retained Territory (if applicable), and (ii) copies of all meeting minutes with any Regulatory Authorities in the Territory and in the Retained Territory (if applicable). In addition, Duality shall provide Licensee with written notice of any scheduled material meeting, conference, or discussion with a Regulatory Authority related to Regulatory Approvals related to the Planned Trials and Licensee Added Trials (if any). Licensee (or its designee) shall have the right to (i) attend and participate in all such meetings with Regulatory Authorities related to the Planned Trials and Licensee Added Trials (if any), and all telephone conferences and preparation meetings of Duality or its Affiliates related to any such meeting, (ii) provide input on the regulatory filings in the Territory and in the Retained Territory (to the extent this impacts the position of Licensee in the Territory), and (iii) have final decision making authority in relation to any unsettled matter between the Parties with respect to

regulatory filings in the Territory. Subject to the foregoing, Licensee (and/or its Affiliates, or Sublicensees as applicable) shall have the sole right to conduct all communications with Regulatory Authorities, including all meetings, conferences and discussions (including advisory committee meetings), with regard to the Licensed Compound and ADC Licensed Products in the Territory, including in respect of the Licensee Added Trials where Licensee (or its Affiliates or Sublicensees, as applicable) is the sponsor (if any). Without limiting the foregoing, the Parties agree that they will collaborate with each other as necessary to ensure the successful progression of interactions with Regulatory Authorities with respect to all trials relating to the Licensed Compound and Original ADC Licensed Products in the Territory and in the Retained Territory (to the extent this impacts the position of Licensee in the Territory).

5.4 [***]. [***], Duality shall transfer and assign, or shall cause the transfer or assignment, to Licensee or its designee (at Duality's cost and expense for Planned Trials and at Licensee's cost and expense for Licensee Added Trials), Duality's, or any of its Affiliates', entire right, title, and interest in and to all IND and other Regulatory Approvals in the Territory, if any, and transfer all Regulatory Materials with respect to the Licensed Compound and Original ADC Licensed Products in the Territory that are owned, controlled or possessed by Duality or any of its Affiliates, unless the Parties agree otherwise.

5.5 Replacement. At any time during the Term, Licensee may decide to replace Duality to be the sponsor of any Planned Trials and Licensee Added Trials (if any) in the Territory. Once Licensee informs Duality by written notice of its decision to replace Duality as the sponsor of any such Clinical Trials in the Territory, Duality shall within [***] days after receipt of such written notice from Licensee (a) transfer to Licensee all Regulatory Materials (including but not limited to the applicable IND, protocol and investigator's brochure) in connection with each of its ongoing Clinical Trials as of the date of such notice and (b) use commercially reasonable efforts to facilitate Licensee's introduction to applicable CROs, study site(s) and investigator(s) in connection with each such Clinical Trial in order to assist Licensee in transferring such Clinical Trial to Licensee, in each case ((a) and (b)) in accordance with Applicable Law and accepted pharmaceutical industry norms and ethical practices. To the extent that the original language of the Regulatory Materials is not English, Duality shall provide a certified full English translation of all documents to Licensee. Licensee shall be responsible for all costs and expenses reasonably incurred by Duality in relation to or as a result of such replacement; provided that if the replacement was caused by a breach of the applicable terms of this Agreement, Applicable Laws or the GXP by Duality, the costs and expenses reasonably incurred by Licensee in relation or as a result of such replacement shall be borne by Duality.

5.6 Data Access; Right of Reference; Access to Regulatory Materials.

[***]

5.7 Pharmacovigilance. Within [***] days of the Effective Date, the Parties shall enter into a pharmacovigilance agreement regarding the Licensed Compound and Original ADC Licensed Products (the "**Pharmacovigilance Agreement**"), which shall set forth standard operating procedures governing the collection, investigation, reporting, and exchange of safety information sufficient to permit each Party to comply with its regulatory and other legal obligations within the applicable timeframes. In the event of any inconsistency between the terms of this Agreement and the Pharmacovigilance Agreement, the terms of this Agreement shall prevail and govern, except to the extent such conflicting terms relate directly to the pharmacovigilance responsibilities of the Parties (including the exchange of safety data), in which case the terms of the Pharmacovigilance Agreement shall prevail and govern. Prior to the Parties entering into the Pharmacovigilance Agreement, Duality is and shall continue to be the owner of the global safety database for the Original ADC Licensed Products. The Pharmacovigilance Agreement can be amended at Licensee's request during the Term and as a

preparation to the Commercialization, at least [***] months' ahead of the first MAA submission. At any time during the Term, upon reasonable prior notice, during regular business hours and under obligations of confidentiality, Licensee (or its designees) shall be entitled to audit (i) any of Duality's or its Affiliates', or any of their respective CROs' or CMOs' manufacturing sites; and (ii) any of Duality's, its Affiliates' clinical sites, as selected by Licensee in its sole discretion, to assess Duality's compliance with all GXP's and all matters arising under the Pharmacovigilance Agreement, in each case of the foregoing (i) and (ii), only in respect of any Clinical Trials run by Duality for Licensee in the Territory; provided that such audit shall not be conducted more than once in any given Calendar Year, unless it is a for-cause audit. If (a) such audit by Licensee identifies any material non-compliance by Duality (via its subcontractors) or its Affiliates (via its subcontractors) of the GXP's or the Pharmacovigilance Agreement in the Territory, and (b) such material non-compliance is confirmed to be an uncured material breach on the part of Duality pursuant to Section 13.3, then the provisions of Section 13.7 shall apply.

5.8 Remedial Actions. Each Party shall notify the other immediately, and promptly confirm such notice in writing, if it obtains information indicating that any Original ADC Licensed Product may be subject to any recall, corrective action, patent regulatory procedures or other regulatory action in the Territory or the Retained Territory by any Governmental Authority or Regulatory Authority (a "**Remedial Action**"). The Parties shall assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. The Parties shall collaborate in good faith and endeavor to reach an agreement on Remedial Action related decisions save that where there is any unsettled issues in relation to any Remedial Action related matters (i) with respect to the Territory, Licensee shall have the final decision making authority and Duality shall take all actions reasonably requested by Licensee in relation to such Remedial Action, save that where such Remedial Action is reasonably likely to impact Duality's position in respect of the Original ADC Licensed Product or any Regulatory Authorities in the Retained Territory, no action will be taken by Licensee (unless immediate action is required to comply with Applicable Laws and mitigate further damage arising from the Remedial Action) without Duality's prior written consent, and (ii) with respect to the Retained Territory, Duality shall have the final decision making authority and Licensee shall take all actions reasonably requested by Duality in relation to such Remedial Action, save that where such Remedial Action is reasonably likely to impact Licensee's position in respect of the Original ADC Licensed Product or any Regulatory Authorities in the Territory, no action will be taken by Duality without Licensee's prior written consent. The cost and expenses of any Remedial Action shall be borne by the Party whose action or inaction caused the Remedial Action of the Original ADC Licensed Product.

ARTICLE 6 MANUFACTURE & SUPPLY

6.1 Costs of CMC Activities. Duality will conduct CMC activities for the Original ADC Licensed Products according to the scope as agreed upon by the Parties in the Development Plan. [***]

6.2 Transfer of CMC Materials from Duality to Licensee. Following the Effective Date (and thereafter from time to time during the Term upon Licensee's reasonable advance request and to the extent not previously provided), Duality shall provide to Licensee (or its designees) the CMC-related technical documents and CMC-related technology (and any associated manufacturing process technology) that are necessary or reasonably useful for the Manufacture of the Licensed Compound and Original ADC Licensed Product and are Controlled by Duality or any of its Affiliates as of the Effective Date and which become Controlled by Duality or any of its Affiliates during the Term ("**CMC Materials**"), and customs and

technology export licenses required by Applicable Law for such transfer(s), if any. Within [***] of Licensee's request, Duality or a Duality CMO shall provide Licensee with reasonable assistance and on-site support in respect of the CMC-related technology and associated manufacturing process technology transferred to Licensee pursuant to this Section 6.2. Any assistance required in excess of [***] will be at the Licensee's cost and expense. To the extent that the original language of the CMC Materials (including Third Party agreements) is not English, Duality shall provide a certified full English translation of these materials. The conclusion of new Third Party agreements regarding the CMC activities contemplated under Section 6.1 or the amendment of existing Third Party agreements regarding the same shall be subject to Licensee's prior written approval.

6.3 Transfer of Cell Lines and Cell Banks. The Parties will enter into a separate quality agreement to manage the logistics and shipping of the transfer of the cell lines and cell banks [***] licensed to Duality pursuant to the Cell Line License Agreement (the "**Cell Lines and Cell Banks**") used for Manufacturing the Antibody incorporated in the Original ADC Licensed Product within [***] days after the Effective Date. [***].

6.4 Initial Clinical Supply. Duality shall, by itself or through one or more Duality CMO(s) in the Retained Territory, supply to Licensee [***] to Licensee's designated [***] and in accordance with a separate clinical supply agreement as contemplated below; provided that Licensee shall be [***]. Unless otherwise agreed by the Parties, the Parties shall negotiate in good faith a clinical supply agreement and related quality agreement with such negotiation to be commenced within [***] days after the Effective Date and completed no later than [***] days after the Effective Date, which clinical supply agreement shall contain customary language regarding supply of the Original ADC Licensed Products to Licensee (including equitable allocation in the event of disruption to or shortage of product supply). [***]

6.5 Ongoing Supply. Except as may otherwise be provided under the clinical supply agreement entered into by the Parties pursuant to Section 6.4 and until the Licensee has qualified a new manufacturing site to Manufacture the Licensed Compound and the Original ADC Licensed Products in the Territory, Licensee shall be solely responsible for (i) Manufacturing the Licensed Compound and Original ADC Licensed Products intended for use in the Territory, and (ii) the associated costs and expenses of such Manufacturing activities, subject to Duality's performance of its obligations under this Agreement. Once the Original ADC Licensed Product is approved, [***]

ARTICLE 7 COMMERCIALIZATION MATTERS

7.1 Overview; Diligence. Subject to the terms and conditions of this Agreement (including the diligence obligations set forth below), Licensee (itself or through its Affiliates or Sublicensees, as applicable) shall be solely responsible for Commercialization of the Original ADC Licensed Products in the Field in the Territory, including: (i) developing and executing a commercial launch and pre-launch plan, (ii) developing the global pricing strategy and negotiating with applicable Governmental Authorities regarding price and reimbursement of the Original ADC Licensed Products; (iii) marketing, advertising and promotion; (iv) booking sales; (v) distribution and handling all aspects of order processing, invoicing and collection, inventory and receivables; (vi) providing customer support, and performing other related functions; (vii) conforming its practices and procedures to Applicable Laws relating to the marketing, detailing and promotion of the Original ADC Licensed Products in the Field; and (viii) developing and implementing the global and local Medical Affairs Activities and medical information infrastructure required in the Field in the Territory. Licensee shall bear all of the costs and

expenses incurred in connection with such Commercialization activities in the Territory. Licensee shall use Commercially Reasonable Efforts to launch the [***] in [***].

7.2 Commercialization Plan. No later than [***] months before the anticipated date of the submission of the first MAA for an Original ADC Licensed Product in the Territory, Licensee shall prepare a written Commercialization plan that sets forth the timeline and details of all major Commercialization activities planned for such Original ADC Licensed Product in the Territory (the “**Commercialization Plan**”). The Commercialization Plan shall be updated at least once a year.

7.3 Coordination of Commercialization Activities. (i) The Parties recognize that they may benefit from the coordination of certain activities in support of the Commercialization of an Original ADC Licensed Product across their territories. As such, the Parties may coordinate such activities where appropriate, including scientific and medical communication and Original ADC Licensed Product positioning. For clarity, Licensee shall not conduct any Commercialization of any Original ADC Licensed Product outside the Territory without Duality’s express prior written consent and Duality shall not conduct any Commercialization of Original ADC Licensed Products outside of the Retained Territory without Licensee’s express prior written consent. (ii) After the exercise of the Cost & Profit/Loss Sharing Option, the Parties will hold [***] meetings which shall serve as a forum for openly discussing the commercialization strategy for the Cost & Profit/Loss Sharing Territory and the Commercialization budget.

7.4 Commercialization Reports.

(a) Licensee shall keep Duality informed of its, its Affiliates’ and Sublicensees’ Commercialization activities in the Territory with respect to each Original ADC Licensed Product and Duality shall keep Licensee informed of Duality’s, its Affiliates’ and sublicensees’ Commercialization activities in the Retained Territory with respect to each Original ADC Licensed Product. All information and reports provided to the other Party in such report shall be treated as Confidential Information of the disclosing Party.

(b) Licensee shall, [***], provide Duality with [***].

(c) In addition to the other provisions of this Section, each Party shall make available to the other Party such additional information about its Commercialization activities with respect to an Original ADC Licensed Product as may be reasonably requested by the other Party from time to time.

7.5 Trademarks. Licensee shall be responsible for the registration, filing, maintenance and enforcement of any trademarks (including domain names) developed for the Original ADC Licensed Products in the Field in the Territory (the “**Product Marks**”). The Parties will discuss in good faith and enter into a separate branding agreement outlining terms for ownership, use, management and enforcement of trademarks (including domain names) adopted to identify the Original ADC Licensed Products in the Field in the Retained Territory.

7.6 Original ADC Licensed Products Tracking in the Territory and Retained Territory . Licensee shall, and shall ensure that its Affiliates and Sublicensees, maintain adequate records to permit the Parties to trace the distribution, sale, and use of all Original ADC Licensed Products through all relevant channels (e.g. wholesalers, hospitals and pharmacies) in the Territory. Duality shall, and shall ensure that its Affiliates and sublicensees, maintain adequate records to permit the Parties to trace the distribution, sale, and use of all Original ADC

Licensed Products through all relevant channels (e.g. wholesalers, hospitals and pharmacies) in the Retained Territory.

7.7 No Diversion. Each Party hereby covenants and agrees that during the Term, and except as expressly permitted by this Agreement, it shall not (and shall cause its Affiliates and Sublicensees (with respect to Licensee), sublicensees (with respect to Duality) and subcontractors not to), either itself or through a Third Party, develop, use, market, promote, import, export, sell or actively offer for sale (online or otherwise) the ADC Licensed Products in the other Party's territory. Without limiting the generality of the foregoing, except as mutually agreed by the Parties, each Party shall not (a) engage in any advertising activities relating to the ADC Licensed Products directed primarily to customers in the other Party's territory, or (b) actively or intentionally solicit orders from any prospective purchaser located in the other Party's territory or prospective purchasers whose delivery address is located in the other Party's territory. To the extent permitted by Applicable Laws, including applicable antitrust laws, if a Party receives any order for ADC Licensed Products from a prospective purchaser located in or with a nominated delivery address in a country or jurisdiction in the other Party's territory, such Party shall immediately refer that order to the other Party and shall not accept any such order or deliver or tender (or cause to be delivered or tendered) the ADC Licensed Products under such order. If a Party should reasonably know that a customer or distributor is actively engaged itself or through a Third Party in the sale or distribution of the ADC Licensed Products in the other Party's territory, then such Party shall (i) within [***] Days of gaining knowledge of such activities, notify the other Party regarding such activities and provide all information available to such Party that the other Party may reasonably request concerning such activities and (ii) use Commercially Reasonable Efforts (including cessation of sales or delivery to such customer) necessary to limit such sale or distribution in the other Party's territory, unless otherwise agreed in writing by the Parties prior to such sale or delivery.

7.8 Co-Promotion Option.

(a) Subject to the terms and conditions of this Agreement, with respect only to the first Original ADC Licensed Product, Licensee hereby grants to Duality an exclusive option during the applicable Co-Promotion Option Period, to assume between [***] and [***] of the total sales force for such Original ADC Licensed Product measured in terms of number of FTEs in the Cost & Profit/Loss Sharing Territory ("**Co-Promotion Option**"); provided that Duality's exercise of the Co-Promotion Option shall not become effective unless Duality satisfies the criteria in Section 7.8(e).

(b) Within [***] days from the Cost & Profit/Loss Sharing Option Exercise Date (the "**Co-Promotion Option Period**"), Duality may during the Co-Promotion Option Period notify Licensee in writing of its desire to exercise the Co-Promotion Option with respect to the first Original ADC Licensed Product (thereafter, the "**Co-Promotion Product**") in the Cost & Profit/Loss Sharing Territory (the "**Co-Promotion Option Exercise Notice**", such date of the Co-Promotion Option Exercise Notice, the "**Co-Promotion Option Exercise Date**").

(i) If Duality elects to exercise the Co-Promotion Option it shall deliver to Licensee the Co-Promotion Option Exercise Notice during the Co-Promotion Option Period, and promptly thereafter the Parties shall engage in good faith negotiations and enter into definitive agreement not later than [***] months (and in any event, to be finalized no later than [***] months prior to the estimated date of the first submission of the MAA in the Cost & Profit/Loss Sharing Territory for the Co-Promotion Product, as set forth in the applicable Development Plan at the Co-Promotion Option Exercise Date) (the "**Co-Promotion Negotiation Period**") from the date of Licensee's receipt of the Co-

Promotion Option Exercise Notice to enter into a co-promotion agreement in accordance with the terms and conditions set out in this Section 7.8 and the Co-Promotion Terms (the “**Co-Promotion Agreement**”). For clarity, the Parties will discuss and agree on the sales force allocation based on the then actual sales force forecast during the Co-Promotion Agreement negotiation period. The Parties shall agree to discuss in good faith to conclude the Co-Promotion Agreement with terms and conditions that are customary for a co-promotion agreement in the Cost & Profit/Loss Sharing Territory; provided that such terms and conditions are consistent with the Co-Promotion Terms. If the Parties are unable to agree on the terms of the Co-Promotion Agreement within the Co-Promotion Negotiation Period, then the Co-Promotion Option shall be deemed to have expired.

(ii) If Duality does not exercise the Co-Promotion Option for the first Original ADC Licensed Product prior to the expiration of the applicable Co-Promotion Option Period, Duality shall be deemed to have irrevocably waived its right to Co-Promote the first Original ADC Licensed Product.

(c) By the latest of [***] months prior to the anticipated launch of the first ADC Original Licensed Product in the Cost & Profit/Loss Sharing Territory, the Parties will coordinate through the SSC to prepare and approve the co-promotion plan (the “**Co-Promotion Plan**”), which Co-Promotion Plan will inter alia set forth (i) all major Co-Promotion activities of the Co-Promotion Product under a single trademark in the Cost & Profit/Loss Sharing Territory to be conducted by the Parties, (ii) an estimated budget related to such Co-Promotion activities, and (iii) an anticipated timeline related to such co-promotion activities.

(d) Under the Co-Promotion Agreement, Licensee shall have the sole right to control all decisions with respect to the Co-Promotion arrangement, including the call plans and assigned states within the Cost & Profit/Loss Sharing Territory covered by Duality’s sales representatives, the promotional materials to be used, the training and testing applicable to such sales representatives, and restrictions with respect to the ability of each Party’s sales representatives to Detail other products; provided that Licensee shall ensure allocation of assigned states and metropolitan and rural territories between the Parties are fair and equitable.

(e) At least [***] months prior to the anticipated launch of the first ADC Original Licensed Product in the Cost & Profit/Loss Sharing Territory, Duality must demonstrate to Licensee by providing adequate documentation (such as CV with a meaningful description of past work experience) that it has a [***] in place (representing the percentage of the total sales force assigned to Duality pursuant to Section 7.8(b)(i)). If Duality cannot demonstrate that it has such a [***] in the Cost & Profit/Loss Sharing Territory at least [***] months prior to the launch of the first Original ADC Licensed Product in the Cost & Profit/Loss Sharing Territory, Duality shall be deemed to have irrevocably waived its right to Co-Promote the first Original ADC Licensed Product in the Cost & Profit/Loss Sharing Territory.

(f) For clarity, this Co-Promotion Option is not sublicensable or transferable to any Third Party and does not apply to the [***], [***] and Sequence Licensed Products.

**ARTICLE 8
FINANCIAL TERMS**

8.1 Upfront Payment. In partial consideration of Duality’s granting of the licenses and rights to Licensee hereunder, Licensee shall make a one-time, non-refundable, non-creditable payment to Duality of [***] (the “**Upfront Payment**”) within [***] days after receipt of an invoice issued by Duality to the Licensee on or after the Effective Date.

8.2 [***].

(a) [***].

(b) **Invoicing.** No later than [***] setting forth the amount of actual Duality Costs for the Planned Trials and Licensee Added Trials (if any) incurred during such Calendar Quarter in the Territory which shall be reimbursed by Licensee pursuant to this Section 8.2, along with supporting documentation itemizing the breakdown of the costs and expenses that were incurred and are reimbursable hereunder. Each invoice issued by Duality shall list Duality Costs [***] in the Territory actually incurred in U.S. Dollars (and if any item was originally in another currency, the exchange rate used for converting the original currency to U.S. Dollar in accordance with Section 9.2). [***]

(c) **Other Clinical Trials.** At Licensee’s request, Duality shall perform any other Clinical Trial of an Original ADC Licensed Product (other than the Planned Trials and Licensee Added Trials). The Parties shall discuss (through the JSC) Licensee’s funding [***].

8.3 Development and Regulatory Milestone Payments of the Original ADC Licensed Product. Subject to Section 8.8(d), with respect to the milestone events set forth in the tables below, promptly following the first achievement, whether by Duality or any of Duality’s Affiliates (when designated by Licensee) or by Licensee or any of Licensee’s Affiliates or Sublicensees, of the corresponding milestone event by the first Original ADC Licensed Product, Licensee or Duality, as the case may be, shall notify the other Party within [***] Days of such achievement, and Licensee shall pay to Duality the corresponding non-refundable, non-creditable milestone payment within [***] days after the receipt of an invoice issued by Duality to Licensee on or after the achievement of the applicable milestone event:

[***]

[***]

[***]

[***]

8.4 Sales Milestone Payments of the Original ADC Licensed Products. Subject to Section 8.8(d), Licensee shall pay to Duality the additional one-time, non-refundable, non-creditable payments set forth in the table below within [***] days after receipt of an invoice issued by Duality to Licensee on or after the first achievement of each milestone event described below. [***].

[***]

Within [***] days after the end of the Calendar Quarter in which any milestone event set forth above in this Section 8.4 for which a milestone payment is payable is achieved, Licensee shall

deliver a written notice to Duality of such achievement, and Licensee shall pay to Duality the corresponding milestone payment within [***] days after the receipt of an invoice issued by Duality to Licensee. For clarity, each of the milestone payments set forth above in this Section 8.4 shall be additive such that if multiple milestone events specified above are achieved in the same Calendar Quarter, then the milestone payments for all such milestone events shall be payable by Licensee.

8.5 Royalties. Licensee shall pay tiered royalties to Duality on Annual Net Sales of: (i) all Original ADC Licensed Products in the Territory in each Calendar Quarter as set forth below in the first table in this Section 8.5 and subject to Section 8.8(f), calculated by [***]; (ii) any [***] and/or [***] at the Reduced Royalty Rates for each respective Annual Net Sales threshold as set forth in the second or third table in this Section 8.5 respectively, calculated by [***]:

[***]

[***]

[***]

8.6 Royalty Term. Royalties under Section 8.5 shall be payable, on a [***] basis, during the period beginning on [***] and continuing until the latest of: [***] (the “**Royalty Term**”).

8.7 Royalty Payment Reduction of ADC Licensed Products.

- (a) [***]
- (b) [***]
- (c) [***]
- (d) [***]

8.8 Effects of Cost & Profit/Loss Sharing Option Exercise for the Original ADC Licensed Product.

- (a) [***]
- (b) [***]
- (c) [***]
- (d) [***]

(e) Sales Milestone Payments for Original ADC Licensed Product.

After exercise of the Cost & Profit/Loss Sharing Option by Duality, in lieu of the sales milestone payments to be made by Licensee to Duality under Section 8.4, Licensee shall pay to Duality the additional one-time, non-refundable, non-creditable payments set forth in the table below after the first achievement of each milestone event described below in the Territory other than Cost & Profit/Loss Sharing Territory:

[***]

(f) **Royalties.**

After exercise of the Cost & Profit/Loss Sharing Option by Duality, in lieu of the royalties to be made by Licensee to Duality under Section 8.5, Licensee shall pay tiered royalties to Duality on Annual Net Sales of all Original ADC Licensed Products in the Territory other than Cost & Profit/Loss Sharing Territory in each Calendar Quarter as set forth below, calculated by [***]. For the avoidance of doubt, Section 8.7 shall apply in determining the royalties to be paid pursuant to this Section 8.8(f):

[***]

8.9 Payments for Other ADC Licensed Products. [***]

8.10 Payments for Sequence Licensed Products. [***]

8.11 [***]

**ARTICLE 9
PAYMENT; RECORDS; AUDITS**

9.1 Payment; Reports. Royalties shall be calculated and reported for each Calendar Quarter within [***] days after the end of each Calendar Quarter. Each payment shall be accompanied by a report of [***]. Except as may otherwise be expressly provided herein, Licensee shall not have the right to set off, withhold or make any deduction from any payment of royalties or other payments due to Duality hereunder for any reason whatsoever.

9.2 Exchange Rate; Manner and Place of Payment. All payments hereunder shall be payable in U.S. dollars within [***] days after receipt of an invoice from Duality. With respect to sales of Licensed Products invoiced in a currency other than U.S. dollars, sales milestones and royalties shall be converted into U.S. dollar using the exchange rate mechanism generally applied by Licensee or its Affiliates or Sublicensees for consolidation purposes, in accordance with the Accounting Standards, for the Calendar Quarter for which a payment is due. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Duality, unless otherwise specified in writing by Duality.

9.3 Taxes.

(a) **Taxes on Income.** Except as otherwise provided in this Section 9.3, Licensee shall be solely responsible for the payment of all value added taxes, fees, duties, surcharges, and other deductions or withholding taxes imposed by or on any entity in the Territory in connection with the payments and activities contemplated hereunder. Except as otherwise set forth in this Section, each Party shall be solely responsible for the payment of all taxes imposed on such Party's income arising directly or indirectly from the activities of the Parties under this Agreement.

(b) **Tax Withholdings.** In the event that any withholding tax, fee, duty or surcharge applicable to or assessable in respect of any of the Upfront Payment, development, regulatory or sales milestone payments, or royalty payments to be made by Licensee to Duality under this Agreement (collectively, the "**License Payments**") is required to be withheld and deducted under Applicable Laws ("**Tax Withholdings**"), Licensee (or its Affiliate paying on behalf of Licensee) shall make such deduction and withholding and will pay the remaining License Payments to Duality. For clarity,

Licensee's reimbursement of Duality Costs in the Territory shall not be deemed to be License Payments or subject to any Tax Withholdings.

(c) **Tax Cooperation.** Licensee shall make such deduction of taxes and withholding tax payments to the applicable taxing authority(ies) in a timely manner and shall promptly provide Duality with the appropriate proof of payment and relevant receipt(s) with respect to such deduction or withholding. To the extent permitted by Applicable Laws, Licensee shall provide Duality reasonable assistance in order to allow Duality to obtain the benefit of any present or future treaty against double taxation or refund or reduction in taxes which may apply to the License Payments. Each Party agrees to use commercially reasonable efforts to cooperate with the other Party in claiming refunds, reductions, or exemptions from such deductions or withholdings under any relevant agreement or treaty that is in effect. Duality will provide Licensee with any tax forms or other documentation reasonably necessary in order for Licensee not to withhold or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. If the taxes originally paid or otherwise borne by a Party are in whole or in part subsequently determined not to have been chargeable, all reasonably necessary steps will be taken by each Party to obtain a refund of these undue taxes from the applicable Governmental Authority or other fiscal authority and any amount of undue taxes repaid by such authority to the receiving Party will be transferred to the paying Party within [***] days of receipt.

9.4 Blocked Currency. In the event that, by reason of Applicable Law in any country or region, it becomes impossible or illegal, after reasonable efforts by Licensee to do so, for Licensee or its Affiliate to transfer, or have transferred on its behalf, payments owed Duality hereunder, Licensee shall promptly notify Duality of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country or region to the credit of Duality in a recognized banking institution designated by Duality provided such arrangements are legal under all Applicable Laws.

9.5 Records; Audits. Licensee shall keep, and require its Affiliates and Sublicensees to keep, complete, fair and true books of accounts and records for the purpose of determining the amounts payable to Duality pursuant to this Agreement. Such books and records shall be kept for at least [***] Years following the end of the Calendar Year to which they pertain. Duality shall have the right to cause an independent, certified public accountant reasonably acceptable to Licensee to audit such records to confirm Net Sales, royalties and other payments for a period covering not more than the preceding [***] Years; provided that (a) such audit shall not be more frequent than once in any [***] month period, and (b) once such accountant has conducted a review and audit of any records pursuant to this Section 9.5 in respect of any given period, it may not subsequently re-inspect such records with respect to such period, unless, in each case of (a) and (b), for cause. Prior to engagement by an independent, certified public accountant, such accountant must have executed and delivered to Licensee and its Affiliates a confidentiality agreement as reasonably requested by Licensee, which will include provisions limiting such accountant's disclosure to Duality to only the results and basis for such results of such inspection. Such audits may be exercised during normal business hours upon reasonable prior written notice to Licensee. Prompt adjustments shall be made by the Parties to reflect the results of such audit. Duality shall bear the full cost of such audit unless such audit discloses an underpayment by Licensee of more than [***] of the amount of royalties or other payments due under this Agreement for any applicable Calendar Quarter, in which case, Licensee shall bear the cost of such audit and shall promptly remit to Duality the amount of any underpayment. Any overpayment by Licensee revealed by an audit shall be fully-creditable against future payment owed by Licensee to Duality (and if no further payments are due, shall be refunded by Duality at the request of Licensee). Any underpayment by Licensee identified by an audit shall not be subject to Section 9.6.

9.6 Late Payments. In the event that either Party fails to make any payment due under this Agreement (save as set out in Section 9.5), simple interest shall thereafter accrue on the sum due from the due date until the date of payment at [***].

ARTICLE 10 CONFIDENTIALITY

10.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party (in such capacity, the “**Receiving Party**”) agrees that, during the Term and for [***] years thereafter, it shall keep confidential and shall not publish or otherwise disclose to any Third Party, and shall not use for any purpose other than as expressly provided for in this Agreement or any other written agreement between the Parties, any Confidential Information, including any Know-How, furnished or made available to it by or on behalf of the other Party (in such capacity, the “**Disclosing Party**”). The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to ensure that its, and its Affiliates’, employees, agents, contractors, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information. The Receiving Party shall promptly notify the Disclosing Party upon discovery of any unauthorized use or disclosure of the Disclosing Party’s Confidential Information.

10.2 Exceptions. Confidential Information shall not include any information which the Receiving Party can prove by competent evidence: (a) is at the time of disclosure, or thereafter becomes, through no act or failure to act on the part of the Receiving Party, generally known or available to the public or part of the public domain; (b) is known by the Receiving Party and/or any of its Affiliates at the time of receiving such information, as evidenced by its records; (c) is hereafter furnished to the Receiving Party and/or any of its Affiliates by a Third Party, as a matter of right and without restriction on disclosure; or (d) is independently discovered or developed by the Receiving Party and/or any of its Affiliates, without the use of or reference to Confidential Information of the Disclosing Party.

10.3 Authorized Disclosure. Notwithstanding the provisions of Section 10.1, the Receiving Party may disclose Confidential Information of the Disclosing Party as expressly permitted by this Agreement, or if and to the extent such disclosure is reasonably necessary in the following instances:

- (a) filing or prosecuting or defending Patents as permitted by this Agreement;
- (b) disclosure required in connection with any judicial, regulatory or administrative process relating to or arising from this Agreement (including any enforcement hereof) or to comply with applicable court orders;
- (c) disclosure to Affiliates, employees, contractors, consultants or agents of the Receiving Party who have a need to know such information in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement; provided, in each case, that any such Affiliate, actual or potential licensee or Sublicensee, employee, contractor, consultant or agent agrees to be bound by terms of confidentiality and non-use comparable in scope to those set forth in this Article 10;
- (d) such disclosure is made to such Party’s attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the Receiving Party, on the condition

that such attorneys, independent accountants and financial advisors are bound by confidentiality and non-use obligations consistent with the confidentiality provisions of this Agreement as they apply to the Receiving Party (provided, however, that in the case of financial advisers, including investment bankers, the term of confidentiality may be shortened to [***] years from the date of disclosure and in the case of attorneys, no written agreement shall be required);

(e) disclosure to existing investors, acquirors or collaborators or potential bona fide investors, acquirors, licensees, Sublicensees or collaborators in connection with due diligence or similar investigations by such Third Parties; provided, in each case, that any such existing or potential investor, acquiror, licensees, Sublicensees or collaborator agrees to be bound by confidentiality and non-use obligations consistent with those contained in this Agreement as they apply to the Receiving Party (but of duration customary in confidentiality agreements entered into for similar purpose);

(f) disclosure to Regulatory Authorities as required by Applicable Laws in relation to Regulatory Approvals and regulatory procedures, proceedings and other filings;

(g) disclosure to: (i) Governmental Authorities to the extent useful or necessary to make regulatory filings and obtain or maintain Regulatory Approvals (including fulfilling post-approval regulatory obligations) for any Licensed Product; (ii) Governmental Authorities, technical committees or similar public health or scientific bodies for purposes of securing product use recommendations, tenders, direct procurement contracts or responding to relevant requests for information; (iii) comply with Applicable Laws with respect to performance under this Agreement; and (iv) to Governmental Authorities in order to respond to inquiries, requests or investigations relating to Licensed Products or this Agreement; and

(h) to the extent mutually agreed to by the Parties in writing.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 10.3(a) or Section 10.3(b), it will, except where impracticable for necessary disclosures, give reasonable advance notice to the other Party of such disclosure requirement and will use its reasonable efforts to secure and cooperate with the other Party, as necessary, to seek and obtain confidential treatment of such Confidential Information required to be disclosed to the extent legally permissible and will limit the disclosure of that Confidential Information required to be disclosure to (i) to advisors (including lawyers and accountants) or Governmental Authorities on a need to know basis, in each case under appropriate confidentiality provisions or professional standards of confidentiality substantially equivalent to those of this Agreement, or (ii) to the extent agreed to by the Parties.

10.4 Public Announcements.

(a) Press Releases and Publicity.

(i) As soon as practicable following the Effective Date and on a date mutually agreed by the Parties, the Parties shall issue a joint press release announcing the execution of this Agreement in substantially the form attached hereto as **Schedule 10.4**. Except as required by applicable securities laws (including disclosure requirements of the U.S. Securities and Exchange Commission ("SEC") or any stock exchange on which securities issued by a Party or its Affiliates are traded), neither Party shall make any other public announcement or statement, whether oral or written, concerning this Agreement or the subject matter hereof without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed; provided that each Party may make any

public statement in response to questions by the press, analysts, investors or those attending industry conferences or financial analyst calls, or issue press releases, so long as any such public statement or press release is not inconsistent with prior public disclosures or public statements approved by the other Party pursuant to this Section 10.4 and which do not reveal non-public information about the other Party. In the event of a required public announcement, to the extent practicable under the circumstances, the Party making such announcement shall provide the other Party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other Party a reasonable opportunity to review and comment upon the proposed text. Licensee shall have final decision making authority in respect of the proposed text of any required public announcement relating to the Licensed Product in the Territory and Retained Territory.

(ii) In the event of termination of this Agreement for any reason, if in the reasonable opinion of the either Party's legal counsel, public disclosure of such termination is required under the Applicable Law or the rules of a stock exchange on which the securities of either Party (or any controlling Affiliate of such Party) are listed (or to which an application for listing has been submitted), the Parties shall cooperate in good faith to coordinate public disclosure, if any, of such termination and the reasons therefor. The principles to be observed in such disclosures shall be accuracy, compliance with Applicable Law, the rules of the applicable stock exchange and regulatory guidance documents, and reasonable sensitivity to potential negative investor reaction to such news and neither Party shall make any other public announcement or statement, whether oral or written, concerning the termination of this Agreement without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed.

(iii) Notwithstanding anything to the contrary in this Section 10.4, and subject to Section 10.5, the Parties have the right to publicly disclose (A) the achievement of milestones under this Agreement; and (B) the commencement, completion, material data and key results of Clinical Trials conducted under this Agreement. After a publication has been made available to the public, each Party may post such publication or a link to it on its corporate web site without the prior written consent of the other Party.

(b) **Filing of this Agreement.** The Parties shall coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the SEC or any stock exchange or governmental agency on which securities issued by a Party or its Affiliate are traded, and each Party will use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; provided that each Party will ultimately retain control over what information to disclose to the SEC or any stock exchange or other governmental agency, as the case may be, and provided further that the Parties will use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither Party (nor its Affiliates) will be obligated to consult with or obtain approval from the other Party with respect to any filings to the SEC or any stock exchange or other governmental agency.

10.5 Publication.

(a) If either Party proposes to publicly present or publish, in any publication or venue, in their respective Territories, any Clinical Trial data, non-clinical data or any associated results or conclusions generated by or on behalf of Licensee pursuant to Clinical Trials (each such proposed presentation or publication, a "**Proposed Publication**"), it shall obtain the other Party's prior written consent and otherwise comply with this Section 10.5. The proposing Party shall provide the other Party with a copy of such Proposed Publication at least [***] days prior to the earlier of its presentation or intended submission for

publication; provided that in the case of abstracts, this period shall be at least [***] Days (such applicable period, the “**Review Period**”). The proposing Party agrees that it will not submit or present any Proposed Publication (i) until the other Party has provided written comments during such Review Period on the material in such Proposed Publication or (ii) until the applicable Review Period (as may be extended by subsection (C) below) has elapsed without written comments from the other Party, in which case the proposing Party may proceed and the Proposed Publication will be considered approved in its entirety. If the proposing Party receives written comments from the other Party during the applicable Review Period, it shall consider the comments of the other Party in good faith, but will retain the sole authority to submit the manuscript for such Proposed Publication; provided that the proposing Party agrees to (A) delete any Confidential Information of the other Party that the other Party identifies for deletion in the other Party’s written comments, (B) delete any Clinical Trial data, non-clinical data, results, conclusions or other related information that is not specific to or resulting from any Clinical Trial conducted in the proposing Party’s territory, and (C) delay such Proposed Publication for a period of up to an additional [***] days after the end of the applicable Review Period to enable the other Party to draft and file patents with respect to any subject matter to be made public in such Proposed Publication and to which the other Party has the applicable intellectual property rights to file such patents. The proposing Party shall provide the other Party a copy of the Proposed Publication at the time of the submission or presentation. The proposing Party shall require its Affiliates, (sub)licensees (in case that Duality is the proposing Party), Sublicensees (in case that Licensee is the proposing Party) and contractors to comply with the obligations of this Section 10.5 as if they were the proposing Party, and shall be liable for their non-compliance.

10.6 Publication and Listing of Clinical Trials. Each Party agrees to comply, with respect to the listing of Clinical Trials or the publication of Clinical Trial information and results with respect to Licensed Products and to the extent applicable to its activities conducted under this Agreement, with any Applicable Law or applicable court order, stipulations, consent agreements and settlements entered into by such Party; provided that any listings or publications made pursuant to this Section 10.6 shall be considered a publication hereunder and shall be subject to Section 10.5.

10.7 Prior Non-Disclosure Agreement. As of the Effective Date, the terms of this Article 10 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) to the extent dealing with the subject of this Agreement. Any information disclosed pursuant to any such prior agreement relating to the subject to this Agreement shall be deemed Confidential Information for purposes of this Agreement.

10.8 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that would result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages would not be a sufficient remedy for any breach of this Article 10. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 10.

ARTICLE 11 REPRESENTATIONS AND WARRANTIES; LIMITATION OF LIABILITY

11.1 Mutual Representations and Warranties. Each Party represents and warrants to the other that, as of the Effective Date:

(a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action;

(c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not (i) conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, (ii) conflict with or result in a breach of any provision of its organizational documents, or (iii) violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and

(d) each Party shall conduct, and shall cause its Affiliates and Sublicensees (in the case of Licensee) and sublicensees (in the case of Duality) to conduct all activities under this Agreement in compliance with all Applicable Laws, all applicable national and international guidelines and any Regulatory Authority and Governmental Authority health care programs having jurisdiction, each as may be amended from time to time.

11.2 Additional Duality Representations and Warranties.

Duality represents and warrants to Licensee, as of the Effective Date and/or such any other date(s) expressly stated, subject to a Disclosure Schedule (attached here to as Schedule 11.2) (the “**Disclosure Schedule**”), as may be updated as further described in Section 11.8 below as follows:

11.2.1 With respect to the [***], the below representations and warranties regarding Licensed Products are given as of the Effective Date but only specifically in relation to [***].

11.2.2 With respect to the [***], the below representations and warranties regarding Licensed Products are given as of the Effective Date but only specifically in relation to [***].

11.2.3 With respect to the [***].

[***]

11.3 Additional Licensee Representations and Warranties. Licensee represents and warrants to Duality, as of the Effective Date:

[***]

11.4 Mutual Covenants. In addition to any covenants made by the Parties elsewhere in this Agreement, each Party hereby covenants to the other that:

(a) (i) all patient authorizations and consents required under Applicable Laws (in connection with any applicable clinical study) permit the granting of access of Data that such Party is required to provide to the other Party pursuant to Section 5.6, and (ii) it will comply with Applicable Laws in transferring personal and other Data in connection with the granting of access of Data that such Party is required to provide to the other Party pursuant to Section 5.6. Each Party will obtain all the necessary authorizations, consents and approvals in order for such Party to grant access to its Data with the other Party, including obtaining the necessary patient authorizations and consents, and obtaining the

necessary approvals from and completing all necessary filing procedures with the applicable Governmental Authorities in the Territory and within the Retained Territory (to the extent required to preserve Licensee's position in the Territory);

(b) it will not knowingly, during the Term, employ or use the services of any person who is debarred or disqualified in connection with activities relating to the Licensed Compound or Licensed Products; and in the event that it becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to it with respect to any activities relating to the Licensed Compound or Licensed Products, it will immediately notify the other Party in writing and it will cease employing, contracting with, or retaining any such person to perform any services relating to the Licensed Compound or Licensed Products;

(c) it shall conduct, and shall cause its Affiliates, subcontractors, Sublicensees (in the case of Licensee) or sublicensees (in the case of Duality) to conduct all activities under this Agreement (including, as set forth in the Development Plan(s) and Commercialization Plan(s) (as may apply) with respect to the ADC Licensed Products in the Field in the Territory) in compliance with all Applicable Laws, and any Regulatory Authority and Governmental Authority health care programs having jurisdiction, each as may be amended from time to time;

(d) it shall conduct its obligations with respect to Development of the ADC Licensed Products in the Territory in adherence with the Development Plan (including the Development Budget) as may be amended from time to time;

(e) it shall comply, and ensure that shall use commercially reasonable efforts to cause its Affiliates, subcontractors and Sublicensees (in case of Licensee) or sublicensees (in case of Duality) to comply with and commit to uphold the ABC Terms in the performance of activities under this Agreement;

(f) it shall have (and shall ensure its Affiliates, Sublicensees (in the case of Licensee) or sublicensees (in the case of Duality) and subcontractors as applicable, have), at all times, a reasonably sufficient number of suitably qualified personnel to allow the Party (or its Affiliates Sublicensees (in the case of Licensee) or sublicensees (in the case of Duality) or subcontractors, as applicable) to conduct, in compliance with all Development timeframes set out in the applicable Development Plans and GXPs, any Clinical Trials that the Party is required to conduct with respect to the Licensed Products in its territory, or in the other Party's territory as permitted under this Agreement; and

(g) it shall not induce or solicit, or attempt to induce or solicit, any employees of the other Party or any of its Affiliates to leave the employment of, or to terminate his/her employment, services or engagement with, the other Party or its applicable Affiliate, or enter into any employment or services agreement or arrangement with such Party or any of its Affiliates.

11.5 Duality Covenants. In addition to any covenants made by Duality elsewhere in this Agreement, Duality hereby covenants to Licensee as follows:

[***]

11.6 Performance by Affiliates, Sublicensees and Subcontractors. (a) Subject to Licensee's prior written consent or if explicitly stated in the Development Plan or this Agreement, Duality may perform some or all of its respective obligations under this Agreement through one or more Affiliates, subcontractors or sublicensees, and (b) Licensee may perform

some or all of its respective obligations under this Agreement through one or more Affiliates, subcontractors or Sublicensees; provided that with respect to the foregoing clauses (a) and (b), the Party involving its Affiliates, subcontractors or Sublicensees (in case of Licensee) or sublicensees (in case of Duality) shall at all times be fully responsible for the performance and payment of such Affiliate, subcontractor or Sublicensees (in case of Licensee) or sublicensees (in case of Duality).

11.7 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY DUALITY TO LICENSEE HEREUNDER ARE PROVIDED “AS IS,” AND DUALITY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OBTAINING SUCCESSFUL RESULTS, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

11.8 Updated Disclosure Schedule

(a) With respect to the [***] (Section 2.9) and the Duality Immune Agonist ADC Product (Section 2.10) that are subject to an option right, and subject to the occurrence of any change or event having a material adverse effect on it or which it believes would or would be reasonably likely to cause or constitute a material breach of any of its representations, warranties or covenants set forth herein. Duality shall be entitled to update the Disclosure Schedule (“**Updated Disclosure Schedule**”) in accordance with this Section 11.8.

(b) The right to update the Disclosure Schedule shall be limited to the respective option exercise period as set forth in Section 2.10 and 2.11 respectively and ends [***] Days before the option exercise period ends.

(c) Notwithstanding anything in this Agreement to the contrary, no update to the Disclosure Schedule pursuant to this Section 11.8 shall cure any breach of a representation or warranty of Duality contained in this Agreement with respect to the ADC Licensed Product and/or Sequence Licensed Product and shall not affect any of the Licensee’s remedies with respect thereto.

ARTICLE 12 INTELLECTUAL PROPERTY

12.1 Ownership.

(a) **Background IP.** (i) Duality shall retain all right, title and interest in and to any Patents, Know-How, and other intellectual property rights Controlled by Duality or any of its Affiliates on or prior to the Effective Date or during the Term independent of the activities hereunder (the “**Duality Background IP**”), and (ii) Licensee shall retain all right, title and interest in and to any Patents, Know-How, and other intellectual property rights Controlled (other than pursuant to this Agreement) by Licensee or any of its Affiliates on or prior to the Effective Date or during the Term independent of the activities hereunder, specifically relating to the ADC (the “**Licensee Background IP**”).

(b) **Solely Owned Collaboration IP and Solely Owned Collaboration Patents.**

(i) [***]

(ii) [***]

(c) [***]

(d) [***]

(e) [***]

(f) [***]

(g) [***]

(h) **Data and Regulatory Materials.** Notwithstanding anything contrary in this Section 12.1, the ownership rights to Regulatory Materials are allocated in accordance with Sections 5.2(b) and 5.4. The ownership rights to Data are allocated in accordance with Section 5.6.

(i) [***]

(j) **Disclosures; Cooperation.** Each Party shall, and shall ensure that each of its Affiliates, (sub)licensees (in the case of Duality), Sublicensees (in the case of Licensee) and subcontractors under this Agreement has a contractual obligation to disclose to such Party all Collaboration IP, Data and other Know-How generated, invented, discovered, developed, made or otherwise created by or for them or their employees, agents or independent contractors, and to provide sufficient documentary proof to evidence ownership, rights and interest with respect thereto, so that such Party can comply with its obligations under this Section 12.1.

(k) **Inventorship Determination.** The Parties agree that [***].

12.2 Patent Prosecution and Maintenance.

(a) **Definition.** For purposes of this Section 12.2 and Sections 12.1(e) and 12.1(f), the terms “prosecute,” “prosecuting” and “prosecution,” when used in reference to any Patent, shall be deemed to include, without limitation, control of any [***] with respect to such Patent.

(b) [***]

(c) [***]

(d) [***]

(e) [***]

12.3 Infringement by Third Parties.

(a) **Notice.** In the event that either Duality or Licensee becomes aware of any infringement or threatened infringement by a Third Party of any Solely Owned Collaboration Patent, Duality Product Patent, Duality Linker-Payload Patent, [***], and any related declaratory judgment or equivalent action, including administrative proceedings, alleging the invalidity, unenforceability or non-infringement of any such Patent, it shall notify the other Party in writing to that effect within [***] Days after becoming aware of such matter.

- (b) [***]
- (c) [***]
- (d) [***]
- (e) [***]
- (f) [***]

12.4 Infringement of Third Party Rights.

- (a) [***]
- (b) [***]
- (c) [***]

12.5 Marking. [***]

12.6 Patent Listings. On a Licensed Product-by-Licensed Product basis, as between the Parties, [***] to make all patent listings of Duality Product Patents, Solely Owned Collaboration Patents, [***] or other patent-related submissions with Regulatory Authorities with respect to such Licensed Product, except for Duality Linker-Payload Patents [***], to make all patent listings *provided that* [***] will be obliged to make all patent listings or other patent-related submissions with Regulatory Authorities in [***]. [***] reasonable requests in connection therewith, including meeting any submission deadlines, to the extent required or permitted by Applicable Laws.

12.7 Patent Right Term Extension. [***]

**ARTICLE 13
TERM; TERMINATION**

13.1 Term. The term of this Agreement (the “**Term**”) shall commence on the Effective Date, and unless terminated earlier as provided in this Article 13, shall continue in full force and effect, on [***] except as provided otherwise in this Article 13.

13.2 [***]

- (a) [***]
- (b) [***]

13.3 Termination for Material Breach by Either Party.

(a) **Termination Right.** A Party shall have the right to terminate this Agreement (in its entirety or on a Licensed Product-by-Licensed Product and country-by-country basis) upon written notice to the other Party if such other Party is in material breach of this Agreement and has not cured such breach within [***] days after written notice from the terminating Party requesting cure of the breach. In case the alleged material breach is a material breach of Licensee’s diligence obligations set forth in Sections 4.1 and/or 7.1 of this Agreement, Duality shall only be entitled to terminate the Agreement with effect to the country or countries with respect to which Licensee has in fact materially

breached the diligence obligations with respect to the Original ADC Licensed Product and not cured such breach. If at the end of the cure period the breaching Party has failed to perform the activities of the cure plan to cure the breach, the non-breaching Party shall be entitled to terminate the Agreement with [***] prior notice. If the existence of material breach or the failure to cure such material breach is not disputed by the breaching Party and the Agreement is terminated by the non-breaching Party, the consequences of termination set forth in Section 13.7 or Section 13.8 (as the case may be) shall apply. If the existence of material breach or the failure to cure such material breach is disputed by the breaching Party, Section 13.7 or Section 13.8 (as the case may be) shall apply if the existence of material breach or the failure to cure such material breach is determined pursuant to Section 15.2 and the Agreement is thereafter terminated by the breaching Party.

(b) **Dispute as to Material Breach.** In the event that the breaching Party disputes the existence of material breach or the failure to cure such material breach by initiating arbitration proceedings pursuant to Section 15.2 within the cure period, the non-breaching Party shall not have the right to terminate in accordance with Section 13.3(a) unless and until the relevant dispute has been resolved pursuant to Section 15.2. During the pendency of such dispute, the applicable cure period shall be tolled, all the terms of this Agreement shall remain in effect, and the Parties shall continue to perform all of their respective obligations hereunder.

13.4 Termination for Other Causes.

(a) [***]

(b) **Bankruptcy.** A Party shall have the right to terminate this Agreement upon written notice to the other Party upon the filing or institution of bankruptcy, reorganization, dissolution, liquidation or winding up of such other Party, or the making or seeking to make or arrange an assignment of a substantial portion of such other Party's assets for the benefit of creditors of such other Party, or the initiation of proceedings in voluntary or involuntary bankruptcy against such other Party, or is adjudged bankrupt, or the appointment of a receiver or trustee of such other Party's property, in each case that is not discharged within [***] days, or immediately upon written notice to the Party, if such Party otherwise admits in writing to the other Party its inability generally to meet its obligations as and when they fall due in the general course of business. In the event a Party is bankrupted or a bankruptcy proceedings is commenced by or against such Party or its Affiliates or any country or jurisdiction, all rights under this Agreement will be fully exercisable and the bankrupt Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall continue to perform all of the obligations provided in this Agreement to be performed by such Party. If the bankrupt Party and its successors and assigns are restricted by Applicable Laws from performing its obligations hereunder and the other Party elects to retain its rights hereunder, then the bankrupt Party shall provide to the other Party copies of all information necessary for such other Party to prosecute, maintain and enjoy its rights under the terms of this Agreement promptly upon such other Party's written request therefor. All rights, powers and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity.

(c) [***]

(d) **Mutual Agreement.** The Parties may terminate this Agreement in full or on a Licensed Product-by-Licensed Product or a country-by-country basis, at any time during the Term upon mutual agreement in writing

13.5 General Effects of Expiration or Termination.

(a) **Accrued Rights and Obligations.** Neither expiration nor any termination of this Agreement for whatsoever reason shall relieve either Party of any obligation or liability (including but not limited to any payment obligation under Article 8) accruing prior to such expiration or termination, nor shall expiration or any termination of this Agreement for whatsoever reason preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement. Such obligations and rights shall survive termination and expiration of this Agreement.

(b) **Termination of Non-Expired Options.** In case of termination of the entire Agreement, all non-expired option periods under the Agreement shall automatically terminate. Upon termination of one or more Licensed Products, the option period shall only terminate with respect to the terminated Licensed Product(s).

(c) **Surviving Terms.** The Parties' rights and obligations under Article 1 (Definitions), Article 8 (Financial Terms, unless otherwise set out in this Article 13, the Financial Terms only survive with respect to Licensee's sell-off right in Sections 13.6(e), 13.7(b)(iv) and 13.8(b)(iii)); Article 9 (Payment); Article 10 (Confidentiality), Section 12.1 and with respect to [***] only Sections 12.2 and 12.4; Sections 13.5 to 13.10; Article 14 (Indemnification) other than Section 14.4 (Insurance); Article 15 (Dispute Resolution); Article 16 (Miscellaneous) of this Agreement shall survive expiration or any termination of this Agreement.

13.6 [***]

13.7 Consequences of Termination by Duality for Material Breach or Patent Challenge by Licensee. If an arbitration tribunal in accordance with the process set out in Section 15.2 confirmed the existence of a material breach on the part of Licensee, and such material breach was not or cannot be cured, or in case of an uncured patent challenge by Licensee (Section 13.4(a)(i)), the following shall apply:

(a) **Duality's Election to Continue.** [***]

(b) **Duality's Election to Terminate.** Duality may, in its sole discretion, elect to terminate the Agreement (in part or in its entirety, as applicable) for material breach in accordance with Section 13.3. The consequences of such a termination for material breach shall be as follows:

(i) **Licenses Granted to Licensee.** In case of a termination of the entire Agreement, [***].

(ii) **Rights Granted to Duality.** In case of termination of the entire Agreement, [***].

(iii) **Wind-Down or Transfer of Activities.** Licensee shall, as directed by Duality in its sole discretion, on a Clinical Trial-by-Clinical Trial basis, either:

(iv) [***]

(v) **Sublicenses.** Duality shall grant to Licensee's or Licensee's Affiliate's Sublicensees a direct license; provided that (A) such sublicense agreement is consistent with the relevant terms and conditions of this Agreement at the time of termination of this

Agreement, (B) such Sublicensee then is not in material breach of its sublicense agreement and (C) such Sublicensee then has not caused Licensee to be in material breach of this Agreement due to any act or omission of such Sublicensee. The scope of such direct license shall be no less than the scope of the license granted in this Agreement and sublicensed to such Sublicensee and such direct license shall be on terms and conditions substantially similar to those set forth in this Agreement.

13.8 Consequences of Termination by Licensee for Material Breach or Patent Challenge by Duality. If an arbitration tribunal in accordance with the process set out in Section 15.2 confirmed (A) the existence of a material breach on the part of Duality, and such material breach was not or cannot be cured, or (B) in case of [***], with the Licensee’s Executive Officer having the final say, the following shall apply:

(a) [***]

(b) [***]

(c) [***]

13.9 [***]

13.10 [***]

ARTICLE 14 INDEMNIFICATION

14.1 Indemnification of Duality. Licensee shall indemnify and hold harmless each of Duality and its Affiliates and their respective directors, officers, employees, consultants, agents and successors and assigns of any of the foregoing (the “**Duality Indemnitees**”) from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys’ fees (“**Losses**”), incurred by any Duality Indemnitee as a result of any claims, demands, actions, suits or proceedings brought by a Third Party (“**Third Party Claims**”) arising directly or indirectly out of: (a) the practice by Licensee or its Affiliates or Sublicensees or subcontractors of the licenses granted to Licensee under this Agreement; (b) the research, Development, Manufacture or have Manufactured, use, handling, storage, Commercialization or other disposition of the Licensed Compound or the Licensed Products by Licensee or its Affiliates or Sublicensees or subcontractors; (c) the negligence or willful misconduct of any Licensee Indemnitee; (d) any breach of any representations, warranties or covenants by Licensee under this Agreement or (e) any breach of the obligations under Section 8.8 or Section 8.9 of this Agreement; except, in each case, (x) to the extent such Third Party Claims fall within the scope of the indemnification obligations of Duality set forth in Section 14.2, or (y) arising from or occurring as a result of a Duality Indemnitee’s negligence, illegal conduct or willful misconduct in performing its or their obligations or exercising their rights under this Agreement. Except as set forth in Clause (e) above, Licensee’s indemnification obligation specifically excludes any and all Third Party Claims for the use of any Patents, Know-How or other intellectual property rights under any Third Party agreements entered into by Duality prior to the Effective Date, including but not limited to the payment of royalties thereunder, other than Third Party Claims arising from or related to Licensee’s failure to make any payment under Section 8.9 or Section 8.10 of this Agreement.

14.2 Indemnification of Licensee. Duality shall indemnify and hold harmless each of Licensee and its Affiliates and their respective directors, officers, employees, consultants, agents

and successors and assigns of any of the foregoing (the “**Licensee Indemnitees**”), from and against any and all Losses incurred by any Licensee Indemnitee as a result of any Third Party Claims arising directly or indirectly out of: (a) the practice by Duality or its Affiliates or sublicensees or subcontractors of the license granted to Duality under Section 2.5; (b) the research, Development, Manufacture or have Manufactured, use, handling, storage, Commercialization or other disposition of the Licensed Compound or Licensed Products by Duality or its Affiliates or sublicensees or subcontractors; (c) the negligence or willful misconduct of any Duality Indemnitee; or (d) any breach of any representations, warranties or covenants by Duality under this Agreement; except, in each case, (x) to the extent such Third Party Claims fall within the scope of the indemnification obligations of Licensee set forth in Section 14.1, or (y) arising from or occurring as a result of a Licensee Indemnitee’s negligence, illegal conduct or willful misconduct in performing its or their obligations or exercising their rights under this Agreement. In addition to the above, and not subject to (x), regardless of any information provided by Duality to Licensee regarding Third Party Agreements entered into prior to the Effective Date, Duality’s indemnification obligation shall cover any and all Third Party Claims for the use of any Patents, Know-How or other intellectual property rights under any Third Party Agreements entered into by Duality prior to the Effective Date, including but not limited to the payment of royalties thereunder, other than Third Party Claims arising from or related to Licensee’s failure to make any payment under Section 8.9 or Section 8.10 of this Agreement.

14.3 Procedure. If any Duality Indemnitee or Licensee Indemnitee intends to claim indemnification under this Article 14 (the “**Indemnitee**”), Duality or Licensee, as the case may be, shall promptly notify the indemnifying Party (the “**Indemnitor**”) in writing of any Third Party Claim, in respect of which the Indemnitee intends to claim such indemnification. Each indemnification claim notice must contain a description of the claim, the nature and amount of such loss (to the extent known at the time). The Indemnitor shall have sole control of the defense and/or settlement thereof and the Indemnitee shall be entitled to participate in (but not control) the defense of such Third Party Claim and to employ counsel of its choice for this purpose, at its own expense. The indemnity arrangement in this Article 14 shall not apply to amounts paid in settlement of any action with respect to a Third Party Claim, if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld, conditioned or delayed unreasonably. The failure to deliver written notice to the Indemnitee within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the Indemnitor of its indemnification obligations under this Article 14 if and to the extent the Indemnitee is actually prejudiced thereby. Duality or Licensee, as the case may be, and the Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Third Party Claim covered by these indemnification provisions. The Indemnitor shall not settle any Third Party Claim without the prior written consent of the Indemnitee if the settlement is reasonably expected to: (a) result in or impose any obligation (including any payment obligation) on the Indemnitee or otherwise adversely affect the business of the Indemnitee in any manner, or (b) result in any admission of wrong-doing or fault by the Indemnitee. The costs and expenses, including fees and disbursements of counsel, incurred by the Indemnitee in connection with any claim shall be reimbursed by the Indemnitor on a Calendar Quarter basis, without prejudice to the Indemnitor’s right to contest the Indemnitee’s right to indemnification and subject to refund in the event the Indemnitee is ultimately held not to be obligated to indemnify the Indemnitor.

14.4 Insurance. Each Party, at its own expense, shall maintain product liability and other appropriate insurance (or self-insure) in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement during the Term. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request. Such insurance shall not be construed to create a limit on either Party’s liability with respect to its indemnification obligations under this Article 14.

ARTICLE 15 DISPUTE RESOLUTION

15.1 Deadlock Resolution. In the event a deadlock occurs with respect to the decision-making process of the JSC, such deadlock shall be subject to binding determination by an expert panel in the Hong Kong Special Administrative Region. The expert panel shall consist of [***] members, [***] of which [***] appointed by each Party and the [***] member shall be selected by the other [***] members (collectively, the “**Experts**”). The panel must be appointed within [***] days of the occurrence of a deadlock event or such longer period as the Parties may agree. Each Expert shall be a person having not less than [***] years’ experience in the area of expertise in the business of pharmaceuticals (including biologics) and having no conflict of interest with either Party. If the issues in dispute involve scientific, technical or commercial matters, the Experts chosen hereunder shall have educational training or industry experience sufficient to demonstrate a reasonable level of relevant scientific, medical and industry knowledge, as necessary to resolve the dispute. With respect to any dispute to be submitted to an Expert pursuant to this Agreement, the use of the Expert shall be the exclusive remedy of the Parties, and neither Party shall attempt to adjudicate such dispute in any other forum. The decision of the Experts shall be final and binding on the applicable Parties involved in such dispute and deadlock resolution procedure contemplated by this Section 15.1 and shall not be capable of challenge, whether by arbitration, in court or otherwise. All proceedings and communications shall be in English.

15.2 Disputes. Subject to Sections 15.4 and 15.5, upon the written request of either Party to the other Party, any differences, claim, dispute, or controversy as to the breach, enforcement, interpretation or validity of this Agreement (a “**Dispute**”) shall be referred to the Executive Officers for resolution. In the event such executives are unable to resolve such Dispute within [***] days after the initial written request, then, upon the written demand of either Party and subject to Section 15.4 below, the Dispute shall be referred to and finally resolved by binding arbitration administered by the Hong Kong International Arbitration Centre (“**HKIAC**”) (or any successor entity thereto) pursuant to the United Nations Commission on International Trade Law (“**UNCITRAL**”) Arbitration Rules in force when the notice of arbitration is submitted, as modified by the HKIAC Procedures for the Administration of Arbitration under the UNCITRAL Arbitration Rules (the “**Rules**”), as modified by Section 15.3 below.

15.3 Arbitration.

Procedure. The arbitration shall be conducted by a panel of three arbitrators experienced in the business of pharmaceuticals (including biologics). If the issues in dispute involve scientific, technical or commercial matters, the arbitrators chosen hereunder shall engage experts having educational training or industry experience sufficient to demonstrate a reasonable level of relevant scientific, medical and industry knowledge, as necessary to resolve the dispute. Within [***] days after initiation of arbitration, each of the Parties shall select one arbitrator and these two arbitrators shall jointly select a third arbitrator. If a Party fails to select an arbitrator or if the two arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator within such [***] day period, any unselected arbitrator or third arbitrator, as the case may be, shall be appointed in accordance with the Rules. The place of arbitration and the seat of arbitration shall be Hong Kong Special Administrative Region, and all proceedings and communications shall be in English. Unless agreed by the Parties in writing, all documents provided under or in connection with this Agreement shall be in the English language or accompanied by a certified English translation. If such document is translated into any other language, the English language version shall prevail unless the document is a constitution, statutory or other official document. The laws governing this arbitration agreement shall be the laws of Hong Kong Special Administrative Region and the arbitral award shall be final and binding on the Parties. Except to

the extent necessary to confirm an award or as may be required by law, neither a Party nor the arbitrators may disclose the existence, content, or results of arbitration without the prior written consent of both Parties.

(a) **Arbitrators' Award.** The arbitrators shall, within [***] days after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the arbitrators shall be final and non-appealable, and judgment may be entered upon it in any court of competent jurisdiction.

(b) **Costs.** Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators; provided, however, that the arbitrators shall be authorized to determine whether a Party is the prevailing party, and if so, to award to that prevailing party reimbursement for any or all of its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, etc.), and/or the fees and costs of the HKIAC and the arbitrators.

(c) **Protective Orders.** At the request of either Party, the Tribunal shall enter an appropriate protective order to maintain the confidentiality of information produced or exchanged in the course of the arbitration proceedings.

15.4 [***]

15.5 Interim Relief. Each Party shall be entitled to take action in any court with competent jurisdiction to apply for and be granted emergency or other interim relief and otherwise enforce by injunction, specific performance or other equitable relief, without prejudice to any other rights and remedies that it may have under this Agreement

15.6 Continued Performance. Provided that this Agreement has not been terminated in its entirety, the Parties agree to continue performing under this Agreement in accordance with its provisions, pending the final resolution of any Dispute.

ARTICLE 16 MISCELLANEOUS

16.1 Rights in Bankruptcy.

(a) The Parties intend to take advantage of the protections of Section 365(n) (or any successor provision) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction to the maximum extent permitted by Applicable Law. All rights and licenses granted under or pursuant to this Agreement, but only to the extent they constitute licenses of a right to "intellectual property" as defined in Section 101 of the U.S. Bankruptcy Code or in any analogous provisions in any other country or jurisdiction (as the case may be) shall be deemed to be "intellectual property" for the purposes of Section 365(n) or any analogous provisions in any other country or jurisdiction (as the case may be). The Parties shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, including the right to obtain the intellectual property from another entity.

(b) In the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party that is not subject to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) all such intellectual property (including all embodiments of such intellectual property), which, if not already in the non-subject Party's possession, shall be promptly delivered to it upon the non-subject Party's written request (i) upon commencement of a bankruptcy proceeding, unless the Party subject to such proceeding continues to perform all of its obligations under this Agreement, or (ii) if not delivered pursuant to clause (i) above because the subject Party continues to perform, upon the rejection of this Agreement by or on behalf of the subject Party.

(c) Unless and until the subject Party rejects this Agreement, the subject Party shall perform this Agreement or provide the intellectual property (including all embodiments of such intellectual property) to the non-subject Party, and shall not interfere with the rights of the non-subject Party to such intellectual property, including the right to obtain the intellectual property from another entity.

16.2 Governing Law. This Agreement and any disputes, claims, or actions related thereto shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflicts of law provisions thereof.

16.3 Entire Agreement; Amendment. This Agreement, including the Schedules hereto, sets forth all of the agreements and understandings between the Parties with respect to the subject matter hereof and thereof, and supersedes and terminates all prior agreements and understandings between the Parties with respect to the subject matter hereof and thereof. There are no other agreements or understandings with respect to the subject matter hereof, either oral or written, between the Parties. Except as expressly set forth in this Agreement, no subsequent amendment, modification or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.

16.4 Further Assurances. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as any other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

16.5 Relationship Between the Parties. The Parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship or legal entity of any type between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever. Neither Party shall treat or report the relationship arising under this Agreement as a partnership for United States tax purposes unless otherwise required pursuant to a determination within the meaning of Section 1313 of the Internal Revenue Code of 1986, as amended.

16.6 Non-Waiver. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and of a particular scope, and shall be signed by such Party.

16.7 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned by a Party without the prior written consent of the other Party (which shall not be unreasonably withheld, conditioned or delayed), except to (a) an Affiliate; provided that this Agreement shall be assigned in whole, and the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate; (b) a Third Party in connection with the sale of all or substantially all of its assets to which this Agreement relates, whether in a sale of stock, sale of assets, business combination, reorganization, or other transaction or series of related transactions. Unless expressly stated otherwise in this Agreement, Duality may assign without the prior consent of Licensee its right to receive payments under this Agreement or grant any security interest in its rights, title and interest in this Agreement, in whole or in part and in their entirety or in portions, to an institutional financier in connection with a financing transaction; provided that Duality has given Licensee a prior written notice regarding such assignment. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the permitted assigns of the Parties. Any assignment not in accordance with this Agreement shall be void.

16.8 Third Party Beneficiaries. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including any third party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby.

16.9 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part. The Parties shall use their commercially reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) in a way that, to the extent practicable and legally permissible, implements the original intent of the Parties.

16.10 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by any method of mail (postage prepaid) requiring return receipt, or by overnight courier or facsimile confirmed thereafter by any of the foregoing, to the Party to be notified at its address(es) given below, or at any address such Party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; (b) if delivered by overnight courier, [***] Business Days after delivery; or (c) if sent by facsimile, upon electronic confirmation of receipt.

if to Duality:

Duality Biologics (Suzhou) Co., Ltd
Unit 1106, No 868 Yinghua Road, Pudong New District, Shanghai,
China

Attention: [***]

Email: [***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

if to Licensee:

BIONTECH SE

[***]

Address: An der Goldgrube 12,
55131 Mainz,
Germany

with a copy to:

[***]

16.11 Force Majeure. Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such Party's reasonable control including but not limited to acts of God, fire, flood, explosion, earthquake, or other natural forces, regional or worldwide epidemic, pandemic, war, civil unrest, acts of terrorism, accident, destruction or other casualty, and a material change in Applicable Law (a "**Force Majeure Event**"). Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused such event(s) to occur. Notice of a Party's failure or delay in performance due to a Force Majeure Event must be given to the other Party within [***] days after its occurrence. The Party affected by a Force Majeure Event will use reasonable efforts to resume performance of its obligations and will keep the other Party informed of actions related thereto. If any such failure or delay in a Party's performance hereunder continues for more than [***] days, the other Party may terminate this Agreement upon written notice to the delayed Party.

16.12 Interpretation. The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. The words "include",

“including”, “containing”, “comprising” and similar words shall not be deemed to be terms of limitation and shall be deemed to be followed by “ without limitation,” whether or not specifically stated and the language following such words shall not be deemed to set forth an exhaustive list. The word “or” means “and/or” unless the context dictates otherwise because the subject of the conjunction are mutually exclusive. The words “herein,” “hereof” and “hereunder” and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. The words “pharmaceuticals” or “drugs” include biologics unless expressly indicated otherwise. All references to days in this Agreement shall mean calendar days, unless otherwise specified. All references to any Applicable Law in this Agreement shall mean such Applicable Law as amended, restated, supplanted or otherwise modified from time to time. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist.

16.13 Construction. The Parties hereto acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in a favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

16.14 Counterparts; Electronic Signatures. This Agreement may be executed in two (2) or more counterparts, including by transmission of facsimile or PDF copies of signature pages to the Parties or their representative legal counsel, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one and the same instrument. Electronic, facsimile or PDF image signatures shall be treated as original signatures, with the understanding that each Party expressly agrees that such Party shall be bound by its own electronically transmitted signature and shall accept the electronically transmitted signature of the other Party (including through the use of eSignature platforms such as DocuSign®). No Party will raise the use of electronic delivery to transmit a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of electronic delivery as a defense to the formation of a contract.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

In Witness Whereof, the Parties hereto have duly executed this **License and Collaboration Agreement** as of the Effective Date.

Duality Biologics (Suzhou) Co., Ltd.

By: /s/ Zhongyuan John Zhu
Name: Zhongyuan John Zhu
Title: Chief Executive Officer

BioNTech SE

By: /s/ Ugur Sahin
Name: Ugur Sahin
Title: Chief Executive Officer

By: /s/ Sean Marett
Name: Sean Marett
Title: Chief Business Officer and Chief Commercial Officer

Schedule 1.1

ABC Terms

1. Each Party agrees that it will not undertake any activities which will result in a violation of any applicable laws, regulations, and applicable industry and professional codes, including but not limited to applicable local and extraterritorial anti-bribery, Anti-Corruption Laws and anti-money laundering laws (collectively "**Prohibited Conduct**") in connection with the performance of any activities under this Agreement.
2. In particular, each Party agrees that during the course of the performance of activities under this Agreement, it (i) shall not make any offer, payment, or promise to pay money or provide anything of value to a Government Official (as defined below) or any other individual and/or legal entity whether directly or indirectly, for the purpose of improperly influencing any act and/or decision of, and/or for securing any improper advantage; (ii) shall not accept, receive, agree to accept and/or receive a payment and/or anything of value from any individual for undue favorable treatment in obtaining, retaining, and/or directing business for, and/or to obtain any undue special concession on behalf of either Party; and (iii) shall not facilitate any payments to any Government Official to expedite a routine government action and/or other official act.
3. The term "**Government Official**" shall include (i) individuals acting on behalf of governments on a national, regional and local level (such as elected officials, customs officials, tax officials, etc.); (ii) individuals acting on behalf of government-owned or government-controlled enterprises; (iii) individuals acting for political parties or as or on behalf of candidates for public office; and (iv) individuals acting on behalf of public international organizations (such as the WHO, World Bank, OECD, etc.).
4. All transactions and expenses incurred on behalf of either Party shall be accurately recorded and maintained in the respective Party's books and records in a timely manner and in reasonable detail in accordance with the applicable generally accepted accounting principles. False, misleading, incomplete, duplicated, inaccurate or artificial entries for the foregoing expenses in a Party's books and records are strictly prohibited.
5. Each Party agrees that if it becomes aware or has reason to suspect that any person or legal entity acting on the Party's and/or the other Party's behalf has engaged in any Prohibited Conduct related to the Agreement, then such Party will promptly report such knowledge or suspicion to the other Party via the following email address: (a) in case that Duality is the reporting party: [***] and (b) in case that Licensee is the reporting party: [***].
6. Duality shall apply Commercially Reasonable Efforts to implement, operate and enforce, without undue delay after the Effective Date, a reasonably designed compliance and business

ethics management and control system that is intended for the prevention and detection of criminal conduct in accordance with applicable Anti-Corruption Laws.

7. Each Party agrees to provide reasonable cooperation in any investigation that may be conducted by or on behalf of the other Party related to the performance of potentially Prohibited Conduct as described in Article 1 above. Upon notice of an intended investigation, a Party will provide, in a reasonable time, to the investigating Party or to a third party engaged by the investigating Party: (a) access to the relevant persons; and/or (b) access to relevant documents and data (e.g., invoices and requests for expense reimbursement, supporting receipts and substantiation, and original entry records for charges and payments).
8. Each Party acknowledges that the obligations under the applicable local and extraterritorial anti-bribery, Anti-Corruption Laws and anti-money laundering laws apply to all its Affiliates and employees, subcontractors and Sublicensees (in case of Licensee) or sublicensees (in case of Duality). Each Party will bind subcontractors who act for or on behalf of such Party to perform activities under this Agreement by such Party for or on behalf of the other Party by respective contractual clauses encompassing all or all material provisions of this Schedule.

Schedule 1.7

Calculation of Adjusted Net Profits

[***]

Schedule 1.38
Co-Promotion Terms

[**]

Schedule 1.76

[***]

[***]

Schedule 1.78

Description of Duality Know-How

[***]

Schedule 1.84
List of Duality Patent Rights

[***]

Schedule 2.7

Initial Know-How Transfer

[***]

Schedule 2.9(b)
[*] Data Package**

[***]

Schedule 8.8(b)(iii)

Illustrative Example for [*] Costs [***]**

[***]

Schedule 8.8(c)

Example [*] Calculation**

[***]

Schedule 8.9

Payments for Other ADC Licensed Products

[***]

Schedule 8.10
Payments for [*] Licensed Products**

[***]

Schedule 10.4
Joint Press Release

[**]

Schedule 11.2
Disclosure Schedule

[***]

*** Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) the type of information that the Registrant treats as private or confidential.

*Execution Version
Confidential*

LICENSE AND COLLABORATION AGREEMENT (TROP2)

by and between

DUALITY BIOLOGICS (SUZHOU) CO. LTD.

and

BIONTECH SE

dated as of August 4, 2023

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Schedule 1.102	Licensed Compound
Schedule 1.141	Preliminary Original ADC Licensed Product Development Plan
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LICENSE AND COLLABORATION AGREEMENT (TROP2)

This License and Collaboration Agreement (the “**Agreement**”) is entered into as of August 4, 2023 (the “**Effective Date**”), by and between **Duality Biologics (Suzhou) Co. Ltd.**, a corporation organized and existing under the laws of the People’s Republic of China (“**Duality**”), having a place of business at Unit 1105-1106, No 868 Ying Hua Road, Pudong New District, Shanghai, China, and **BioNTech SE**, a company organized and existing under the laws of Germany, having a place of business at An der Goldgrube 12, D-55131 Mainz, Germany (“**Licensee**”).

Recitals

Whereas, Duality is a clinical stage company focusing on the discovery and development of the next generation ADC therapeutics to treat patients in cancer and autoimmune diseases;

Whereas, Licensee is engaged in the research, development and commercialization of active immunotherapies for patient-specific approaches to the treatment of diseases;

Whereas, Licensee desires to obtain from Duality, and Duality desires to grant to Licensee, an exclusive sublicensable license under the Duality Licensed IP to research, Develop, Manufacture and Commercialize the Licensed Products in the Field in the Territory (each as defined below), subject to the terms and conditions of this Agreement; and

Whereas, the Parties desire to collaborate in the research, Development, Manufacture and Commercialization of the Original ADC Licensed Products and/or after Next Generation Option Exercise, the Next Generation ADC Licensed Products (each as defined below) in accordance with the terms and conditions of this Agreement.

Now, Therefore, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Duality and Licensee hereby agree as follows:

Article 1 DEFINITIONS

1.1 “**ABC Terms**” shall mean those terms set out in **Schedule 1.1** of this Agreement.

1.2 “**Accounting Standards**” shall mean with respect to a Selling Party (as defined below), International Financial Reporting Standards endorsed by the European Union or other applicable standard accounting principles used by Sublicensees.

1.3 “**ADC**” shall mean any construct comprising an Antibody(ies) linked to a non-Antibody chemical species with a therapeutic or biological activity or function, including non-Antibody chemical species that (i) directly kills, slows or stops the growth of a tumor cell through such compound’s primary mechanism of action (“**Cytotoxic Payload**”) or (ii) [***].

1.4 “**Additional Active(s)**” shall mean any active pharmaceutical or biologic ingredient(s) or agent(s) that is not the Licensed Compound.

1.5 “**Affiliate**” shall mean any company or entity controlled by, controlling, or under common control with a Party or another entity. For the purpose of this definition, an entity shall be deemed to “**control**” another entity, if it owns directly or indirectly, more than fifty percent (50%) of the outstanding voting securities, capital stock, or other comparable equity or ownership interest of such entity, or possession, direct or indirect, of the power to direct or cause the direction of the management or policies of an entity (whether through ownership of securities or other ownership interests, by contract or otherwise).

1.6 “**Alliance Manager**” shall have the meaning provided in Section 3.10.

1.7 “**Annual Net Sales**” shall mean for a particular Licensed Product the total Net Sales for a particular Calendar Year.

1.8 “**Antibody**” shall mean any antibody (including murine, chimeric, human, humanized, recombinant, transgenic, grafted, phage display derived, or single chain antibody), or antigen binding fragment thereof. [***]

1.9 “**Anti-Corruption Laws**” shall mean all applicable anti-bribery and anti-corruption laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, the U.K. Bribery Act 2010 and the PRC Anti-Money Laundering Law and the comparable Applicable Laws of any countries in which candidates or Licensed Products, payments or services will be provided or procured under or pursuant to this Agreement.

1.10 “**Applicable Data Protection Law**” shall mean all Applicable Laws in any jurisdiction relating to privacy or the processing or protection of personal data or personal information, including the General Data Protection Regulation (EU) 2016/679 (GDPR), the UK Data Protection Act 2018, the e-Privacy Directive (2002/58/EC) and the comparable in other jurisdictions and all guidance issued by any applicable data protection authority.

1.11 “**Applicable Laws**” shall mean collectively the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, of any Governmental Authority and any license, franchise, permit or similar right granted under any of the foregoing (including Regulatory Approvals) and any policies and other requirements of or from any court, arbitrator, Regulatory Authority or governmental agency or Governmental Authority having jurisdiction over or related to the subject item or subject person, including all applicable GXPs, Anti-Corruption Laws, Applicable Data Protection Laws, accounting and recordkeeping laws, export control laws and laws relating to interactions with health care professionals and Government Officials (as defined in Schedule 1.1).

1.12 “**Biologics License Application**” or “**BLA**” shall mean an application requesting permission from the FDA to introduce, or deliver for introduction, a biological product into interstate commerce.

1.13 “**Biosimilar Product**” shall mean with respect to a particular Licensed Product in a given country, a product comprising an ADC sold by a Third Party not authorized by Licensee or its Affiliates or Sublicensees that is approved by the applicable Regulatory Authority for such country through an application or submission filed with a Regulatory Authority for marketing approval of a biologic product claimed to be biosimilar or interchangeable to such Licensed Product, including an application filed under 42 U.S.C. § 262(k) (or any successor thereto) or any similar laws or regulations in a country

outside the United States in reliance on data generated for a Regulatory Approval of such Licensed Product.

1.14 “Business Day” shall mean any day that is not a Saturday, a Sunday or any other day on which banks are required or authorized by law to close in Mainz, Rhineland-Palatine (in Germany) or any government mandated holiday in Mainland China.

1.15 “Calendar Quarter” shall mean each period of three (3) consecutive months commencing on January 1, April 1, July 1 or October 1 (or any portion thereof at the beginning or end of the Term or other relevant period).

1.16 “Calendar Year” shall mean each period of twelve (12) consecutive months commencing on January 1 and ending on December 31 (or any portion thereof at the beginning or end of the Term or other relevant period).

1.17 “Cell Banks” shall have the meaning provided in Section 6.3.

1.18 “Change of Control” shall mean, with respect to either Party: (a) a merger, acquisition, reorganization, or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, acquisition, reorganization, or consolidation; (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner, directly or indirectly, of more than fifty percent (50%) of the combined voting power of the outstanding securities of such Party; or (c) a transfer to a Third Party of all or substantially all of its assets relating to this Agreement.

1.19 “Clinical Trial” shall mean a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, Registrational Trial or other human clinical trial conducted after the Regulatory Approval of a product in a country, which trial may be conducted to (a) enhance scientific knowledge of such product (e.g., for expansion of product labeling), (b) due to a request or requirement of a Regulatory Authority in such country, (c) is otherwise designed to establish that a product is reasonably safe for continued testing and to identify adverse reactions and ascertain the safety of the product, or (d) investigate the safety and efficacy of the product for its intended use, and to define warnings, precautions and adverse reactions that may be associated with the product in the dosage range to be prescribed.

1.20 “CMC” shall mean chemistry, manufacturing and controls with respect to the Licensed Compound or Licensed Products.

1.21 “CMC Materials” shall have the meaning provided in Section 6.2.

1.22 “CMO” shall mean Third Party contract manufacturing organization.

1.23 “Collaboration IP” shall mean [***].

1.24 “Combination Product” shall [***].

1.25 “Commercialization” shall mean, with respect to a product, any and all activities undertaken before and after obtaining Regulatory Approvals relating specifically to the pre-launch, launch, promotion, detailing, marketing, pricing, reimbursement, sale, importing, exporting or transporting such product, and distribution of such product,

including strategic marketing, sales force detailing, advertising, market product support, all customer support, product distribution, and invoicing and sales activities, but excluding Development and Manufacturing. “Commercialize”, “Commercialized” and “Commercializing” shall have the correlative meanings.

1.26 “Commercialization Phase” would mean [***].

1.27 “Commercialization Plan” shall have the meaning provided in Section 7.2.

1.28 “Commercially Reasonable Efforts” shall mean, [***].

1.29 “Committee” shall have the meaning given in Section 3.4.

1.30 “Competing Product” shall mean, [***].

1.31 “Competitive Change of Control” shall mean a Change of Control of Duality where the incoming Third Party and/or its Affiliates is a Competitor.

1.32 “Competitor” shall mean [***].

1.33 “Confidential Information” shall mean all Know-How and other proprietary scientific, technical, clinical, marketing, financial or commercial information or Data Controlled by a Party or its Affiliates, which one Party or any of its Affiliates has furnished or made available to the other Party or its Affiliates, whether in oral, written or electronic form. The existence and terms of this Agreement shall be deemed Confidential Information of each Party.

1.34 “Control” (including any variations such as “Controlled” and “Controlling”) shall mean, with respect to any Know-How, Patents or other intellectual property rights, possession by a Party or Third Party of the right, power and authority (whether by ownership, license, sublicense or otherwise, other than by virtue of any rights granted under this Agreement) to grant access to, to grant use of, or to grant a license or a sublicense to such Know-How, Patents or intellectual property rights without violating the terms of any agreement or other arrangement with any Third Party. Notwithstanding anything in this Agreement to the contrary, a Party and its Affiliates will be deemed to not Control any Know-How, Patents, or other intellectual property rights that are in-licensed or acquired by such Party or its Affiliates from a Third Party after the Effective Date, unless the other Party agrees to (a) comply with the terms and conditions of the agreement under which such Know-How, Patents, or other intellectual property rights were in-licensed or acquired by such Party; and (b) pay all amounts that such Party would be obligated to pay in connection with the grant, maintenance and exercise of a (sub)license as reasonably allocable to such other Party for use in its territory under such Know-How, Patents, or other intellectual property rights.

1.35 “Cover” shall mean, [***].

1.36 “CRO” shall mean a contract research organization.

1.37 “Data” shall mean all data, including non-clinical data, preclinical data and clinical data, including pharmacological, biological, chemical, toxicological, clinical test, safety, clinical and analytical information, quality control, trial, stability and manufacturing processes and techniques data generated by or on behalf of a Party or its Affiliates or their respective Sublicensees (in case of Licensee) and (sub)licensees and

other (sub)contractors (in the case of Duality) pursuant to activities conducted under this Agreement.

1.38 [***]

1.39 **“Development”** shall mean, with respect to a pharmaceutical or biological product, any research activities, all non-clinical and clinical drug development activities and processes, [***] regulatory affairs and other activities, in each case, which are reasonably necessary to prepare submissions for, and obtain or maintain, Regulatory Approval of such product and interacting with Regulatory Authorities regarding the foregoing, including lifecycle management studies and other activities. **“Develop”**, **“Developed”**, and **“Developing”** shall have the correlative meanings.

1.40 **“Development Budget”** shall mean the Original ADC Licensed Product Development Budget and/or the Next Generation Development Budget, as the context admits.

1.41 **“Development Costs”** shall mean [***].

1.42 **“Development Phase”** shall mean the phase starting with the Effective Date to the First Commercial Sale of a Licensed Product during which either Party is conducting Development activities for such Licensed Product or Licensed Compound, or after Next Generation Option Exercise, the Next Generation ADC Licensed Product or Next Generation Licensed Compound.

1.43 **“Development Plan”** shall mean the Original ADC Licensed Product Development Plan and/or the Next Generation Development Plan, as the context admits.

1.44 **“Disclosing Party”** shall have the meaning provided in Section 10.1.

1.45 **“Disclosure Schedule”** shall have the meaning provided in Section 11.2.

1.46 **“Dispute”** shall have the meaning provided in Section 15.2.

1.47 [***]

1.48 **“Duality Background IP”** shall have the meaning provided in Section 12.1(a).

1.49 **“Duality CMO”** shall mean any CMO engaged by Duality or any Affiliate of Duality.

1.50 **“Duality Competing Product”** shall mean [***].

1.51 **“Duality Costs”** shall mean any and all costs and expenses that are reasonably incurred by or on behalf of Duality and its applicable Affiliates after the Effective Date in conducting the Planned Trials, the Next Generation Added Trials and/or performing other Development activities as agreed hereunder in the Territory pursuant to this Agreement and the respective Development Plan. [***]

1.52 **“Duality Development Activities”** shall have the meaning provided in Section 4.4(a).

1.53 “**Duality Immune Agonist ADC Product**” shall have the meaning provided in Section 2.8.

1.54 “**Duality In-Licensed Agreements**” shall mean each Agreement as set forth on **Schedule 1.54**.

1.55 “**Duality In-Licensed IP**” shall mean any and all Patents or Know-How that is Controlled by Duality or any of its Affiliates pursuant to the Duality In-Licensed Agreements.

1.56 “**Duality Indemnitees**” shall have the meaning provided in Section 14.1.

1.57 “**Duality Know-How**” shall mean any and all Know-How (including Data) that (a) is Controlled by Duality or any of its Affiliates as of the Effective Date or at any time during the Term, and (b) are necessary or reasonably useful for the Development, Manufacture or Commercialization of or to otherwise exploit the Licensed Compound or Licensed Products, and/or after Next Generation Option Exercise, the Next Generation Licensed Compound or Next Generation ADC Licensed Products, in the Field in the Territory, including but not limited to, with respect to (a) and (b), the Know-How (including Data) contained in Duality Solely Owned Collaboration IP, [***]. Notwithstanding the foregoing, Duality Know-How shall not include (i) any Know-How (including Data) Controlled by any Third Party that becomes an Affiliate of Duality after the Effective Date as a result of a merger, acquisition or other similar transaction, unless such Know-How (including Data) is used by either Party in the Development, Manufacturing or Commercialization of the Licensed Compound or Licensed Products, and/or after Next Generation Option Exercise, the Next Generation Licensed Compound or Next Generation ADC Licensed Products, and (ii) any Know-How that is related to any Additional Active or other proprietary compound or product Controlled by Duality or any of its Affiliates. A description of Duality Know-How as of the Effective Date is attached hereto on **Schedule 1.57**.

1.58 “**Duality Licensed IP**” shall mean Duality Know-How and Duality Patents. Duality Licensed IP includes Duality In-Licensed IP.

1.59 “**Duality Linker-Payload**” shall mean [***].

1.60 “[***]” shall mean any new or useful invention, discovery, adaptation, redesign, modification, improvement, enhancement, contribution or other desirable change generated in the course of performing activities under this Agreement solely relating to [***]. [***]

1.61 [***]

1.62 “**Duality Linker-Payload Patents**” shall mean any and all Patents claiming the Duality Linker-Payload.

1.63 “**Duality Patents**” shall mean any and all Patents [***].

1.64 “**Duality Product Patents**” shall mean any and all [***]

1.65 “**Duality Solely Owned Collaboration IP**” shall have the meaning provided in Section 12.1(b).

1.66 “**Duality Solely Owned Collaboration Patents**” shall have the meaning provided in Section 12.1(b).

1.67 “**Effective Date**” shall have the meaning provided in the introductory paragraph of this Agreement.

1.68 “**Election Notice**” shall have the meaning provided in Section 2.13.

1.69 “**EMA**” shall mean shall mean the European Medicines Agency and any successor entity thereto.

1.70 “**Executive Officers**” shall have the meaning provided in Section 3.6(a).

1.71 “**Experts**” shall have the meaning provided in Section 15.1.

1.72 “**FDA**” shall mean the U.S. Food and Drug Administration and any successor entity thereto.

1.73 “**Field**” shall mean all uses.

1.74 “**First Commercial Sale**” shall mean, with respect to a Licensed Product, [***].

1.75 “**Force Majeure Event**” shall have the meaning provided in Section 16.11.

1.76 “**FTE**” shall mean the equivalent of a full-time individual’s work time for a twelve (12) month period devoted to performing activities under the Agreement, where “full-time” is determined by [***] hours per Calendar Year. In the event that any individual who works full-time during a given Calendar Year works partially on the activities under this Agreement and partially on other work outside this Agreement, then the full-time equivalent to be attributed to such individual’s work hereunder for such Calendar Year shall be equal to the percentage of such individual’s total work time in such Calendar Year that such individual spent working on activities under this Agreement.

1.77 “**FTE Rate**” shall mean [***] for the first [***] years from the Effective Date. After the [***] anniversary of the Effective Date, the FTE rate will be adjusted on an annual basis based on the higher of (i) the average inflation rate in the countries of the Territory where the Development activities are performed by Duality or (ii) the average salary increase in the relevant categories of Duality’s employees who participate in the project on the FTE basis; provided in either case that any such increase of FTE Rate each year shall not be more than [***].

1.78 “**Fully Burdened Manufacturing Cost**” shall mean, with respect to any Original ADC Licensed Product, or after Next Generation Option Exercise, a Next Generation ADC Licensed Product, supplied by or on behalf of Duality: [***].

1.79 “**GCLP**” shall mean any and all applicable laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the treatment of human laboratory samples from Clinical Trials, including the relevant principles from GCP and the EMA’s reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples, as amended from time to time.

1.80 “GCP” shall mean any and all applicable laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the ethical conduct of Clinical Trials, including without limitation the U.S. Code of Federal Regulations (CFR) Title 21, ICH GCP Guidelines E6(R2) as amended from time to time, national legislation implementing European Community Directive 2001/20/EC (if and as still applicable), European Community Directive 2005/28/EC, and, following the applicable transition periods, the Clinical Trial Regulation (EU) No. 536/2014 (the “CTR”) and the rules, regulations and guidelines applying in the context of the CTR, and the equivalent in other countries or regions.

1.81 “Global Trial” shall mean a Clinical Trial designed to obtain Regulatory Approvals for a Licensed Product in multiple countries through the conduct of a Clinical Trial in multiple countries, regions and/or medical institutions and conducted as part of one (1) unified Clinical Trial or separately but concurrently in accordance with a common Clinical Trial protocol.

1.82 “GLP” shall mean any and all applicable laws, rules, regulations, guidelines and generally accepted standards and requirements regarding quality control for laboratories to ensure the consistency and reliability of results, including without limitation the CFR Title 21, national legislation implementing European Community Directives 2004/9/EC and 2004/10/EC as amended, and the OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, and the equivalent in other countries or regions. For the purposes of this Agreement, GLP also includes the principles of Good Clinical Laboratory Practice and applicable guidelines promulgated under the ICH guidelines.

1.83 “GMP” shall mean any and all applicable laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the quality control and manufacturing of pharmaceutical products, including without limitation the CFR Title 21, Parts 11, 210, 211, 600 and 610, applicable ICH Guidelines including without limitation Q7 for “Active Pharmaceutical Ingredients”, national legislation implementing European Community Directive 2001/83/EC and Commission Directive 2003/94/EC as amended, EudraLex – Volume 4 of the Rules Governing Medicinal Products in the European Union including annexes, the CTR, Commission Delegated Regulation 2017/1569, the Detailed Commission Guideline (2017) 8179, and the equivalent in other countries or regions.

1.84 “Governmental Authority” is to be broadly interpreted and includes any multi-national or public international organization or authority, national, federal, state, local, municipal, provincial, foreign government or other governmental authority of any nature (including any governmental division, prefecture, branch, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal, or body entitled to exercise any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power, and any Regulatory Authority).

1.85 “GXP” shall mean collectively, all relevant and applicable good practice quality guidelines and regulations, encompassing such internationally recognized standards as GMP, GCP, GLP and GCLP, Good Distribution Practice (GDP), Good Pharmacovigilance Practice, Good Pharmacoepidemiology Practice and Good Review Practice.

1.86 “[***] Agreement” shall mean [***].

1.87 “HKIAC” shall have the meaning given in Section 15.2.

1.88 “**ICH**” shall mean the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use.

1.89 “**Immune Agonist ADC Product**” shall mean [***].

1.90 “**IND**” shall mean an investigational new drug application, clinical study application, Clinical Trial exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

1.91 “**IND Data Package**” shall have the meaning provided in Section 2.8.

1.92 “**Indemnitee**” shall have the meaning provided in Section 14.3.

1.93 “**Indemnitor**” shall have the meaning provided in Section 14.3.

1.94 “**Indication**” shall mean, [***].

1.95 “**JDC**” shall have the meaning provided in Section 3.3(b).

1.96 “**JIPC**” shall have the meaning provided in Section 3.3(a).

1.97 “[***]” shall have the meaning provided in Section 12.1(d).

1.98 “[***]” shall have the meaning provided in Section 12.1(d).

1.99 “**JSC**” shall mean the joint steering committee to be established by the Parties pursuant to Section 3.1.

1.100 “**Know-How**” shall mean any and all technical, scientific, regulatory and other information, trade secrets, results, knowledge, techniques, materials (including cell lines) and data, in whatever form and whether or not confidential, proprietary, whether or not patentable, invention disclosures, plans, inventions, assays, designs, protocols, and formulas, processes, practices, methods, knowledge, know how, skill, experience, ideas, concepts, test data (including pharmacological, toxicological and clinical test data), analytical and quality control data, formulae, specifications, marketing, pricing, distribution, cost, sales, and manufacturing data or descriptions. “Know-How” includes any rights including copyright, database or design rights protecting such Know-How. For clarity, Know-How does not include issued Patents, published patent application or the inventions claimed thereby.

1.101 “**License Payments**” shall have the meaning provided in Section 9.4(b).

1.102 “**Licensed Compound**” shall mean the ADC developed by or on behalf of Duality and known as DB-1305 comprising [***] (as described in Schedule 1.102) and the Duality linker-payload known as L10P1021, the structures of which has been provided to Licensee in writing.

1.103 “**Licensed Product**” shall mean any pharmaceutical product, in any dosage form, formulation, presentation, route of administration or package configuration containing the Licensed Compound and/or, upon Licensee’s option exercise, the Next Generation Licensed Compound as an active pharmaceutical ingredient, including but not be limited to (i) the Original ADC Licensed Product, (ii) after Next Generation Option

Exercise, the Next Generation ADC Licensed Product, (iii) [***], and (iv) [***]. The Licensed Product shall further include Combination Products.

1.104 “**Licensee Background IP**” shall have the meaning provided in Section 12.1(a).

1.105 “**Licensee Competing Product**” shall mean, [***].

1.106 [***]

1.107 “**Licensee Indemnitees**” shall have the meaning provided in Section 14.2.

1.108 “**Licensee Know-How**” shall mean any and all Know-How that is Controlled by Licensee or any of its Affiliates and that is comprised by the Licensee’s Solely Owned Collaboration IP. Notwithstanding the foregoing, Licensee Know-How shall not include (i) any Know-How Controlled by any Third Party that becomes an Affiliate of Licensee after the Effective Date as a result of a merger, acquisition or other similar transaction, unless such Know-How is used by Licensee in the Development, Manufacture or Commercialization of the Licensed Compound or Original ADC Licensed Products or after Next Generation Option Exercise, the Next Generation ADC Licensed Product, and (ii) any Know-How that is related to any Additional Active or other proprietary compound or product Controlled by Licensee.

1.109 “**Licensee Licensed IP**” shall mean the Licensee Know-How and Licensee Patents.

1.110 [***]

1.111 “**Licensee Patents**” shall mean any and all Patents that are Controlled by Licensee or any of its Affiliates and that are comprised by the Licensee Solely Owned Collaboration Patents. Notwithstanding the foregoing, Licensee Patents shall not include (i) any Patent Controlled by any Third Party that becomes an Affiliate of Licensee after the Effective Date as a result of a merger, acquisition or other similar transaction, and (ii) any Patent that Covers any Additional Active or other proprietary compound or product Controlled by Licensee provided that such Patent does not Cover the Licensed Compound or Original ADC Licensed Product, or after Next Generation Option Exercise, the Next Generation ADC Licensed Product.

1.112 “**Licensee Sole Development**” shall have the meaning provided in Section 4.3(c)(v).

1.113 “**Licensee Sole Development Data**” shall have the meaning provided in Section 4.3(c)(v).

1.114 “**Licensee Solely Owned Collaboration IP**” shall have the meaning provided in Section 12.1(b).

1.115 “**Licensee Solely Owned Collaboration Patents**” shall have the meaning provided in Section 12.1(b).

1.116 “**Losses**” shall have the meaning provided in Section 14.1.

1.117 “**MAA**” shall mean an application to a Regulatory Authority for the authorization to place a product on the market in the applicable country, region or a

regulatory jurisdiction, including New Drug Application and Biologics License Application, and shall include all amendments and supplements thereto, filed with the applicable Regulatory Authority to gain authorization to place such product on the market in the applicable jurisdiction.

1.118 “**MAH**” shall mean the holder of the Marketing Authorization.

1.119 “**Mainland China**” shall mean the mainland of the People’s Republic of China.

1.120 “**Major [***] Market**” shall mean [***].

1.121 “**Manufacture**” shall mean, with respect to a Licensed Product, activities related to the manufacture and supply of such Licensed Product, including manufacturing supplies for Development or Commercialization, packaging, labeling, in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance and quality control activities related to manufacturing and release of product, ongoing stability tests, storage, and shipment and regulatory activities directly related to any of the foregoing, but not including any Development or Commercialization activities. “**Manufactured**” and “**Manufacturing**” shall have the correlative meanings.

1.122 “**Manufacturing IP**” shall mean any Patents and Know-How that (i) are generated, developed or conceived during the course of performing activities under this Agreement depending on Duality Licensed IP, and (ii) specifically related to, and (iii) are necessary for the Manufacture of the Duality Linker-Payload; notwithstanding the foregoing, Manufacturing IP shall exclude Licensee Background IP.

1.123 “**Marketing Authorization**” shall mean the authorization by all relevant Regulatory Authorities of an MAA in a given country or regulatory region/jurisdiction and the granting of the required authorization for the sale of a product which will include any Pricing and Reimbursement Approvals if required by Applicable Law of the respective country to initiate marketing and selling of a product in such particular country.

1.124 “**MCB**” shall mean the master cell bank.

1.125 “**Medical Affairs Activities**” shall mean the coordination of medical information requests and field based medical scientific liaisons with respect to an Original ADC Licensed Product or after Next Generation Option Exercise, Next Generation ADC Licensed Product, including activities of medical scientific liaisons, activities involving key opinion leaders, and the provision of medical information services with respect to an Original ADC Licensed Product or after Next Generation Option Exercise, Next Generation ADC Licensed Product.

1.126 “**Multi-Specific ADC Product**” shall mean [***].

1.127 “**Negotiation Period**” shall have the meaning set forth in Section 2.13.

1.128 “**Net Sales**” shall mean, [***]

(a) [***]

(b) [***];

(c) [***];

(d) [***]

(e) [***].

[***]

1.129 “**Next Generation ADC Licensed Product**” shall mean any pharmaceutical product, in any dosage form, formulation, presentation, route of administration or package configuration containing the Next Generation Licensed Compound as an active pharmaceutical ingredient, but excluding any Additional Actives.

1.130 “**Next Generation Data Package**” shall mean the package of data and information that shall be provided by Duality to the Licensee in order to assess the Pre-Clinical Proof-of-Concept of the Next Generation Licensed Compound and the Next Generation ADC Licensed Product.

1.131 “**Next Generation Development Budget**” shall have the meaning as set out in Section 1.132.

1.132 “**Next Generation Development Plan**” shall mean a written plan approved by the JSC, and amended from time to time in accordance with the terms of this Agreement, describing (i) the Development strategy for the Next Generation Licensed Compound and Next Generation ADC Licensed Product in the Territory and (ii) the material pre-clinical studies, Clinical Trials and regulatory activities proposed to be performed with respect to the Next Generation ADC Licensed Product as well as (iii) the associated budget regarding the Development activities, including but not limited to the Development Costs, such as the costs for the Development activities performed by Licensee, its Affiliates or its subcontractors as well as the Duality Costs (“**Next Generation Development Budget**”). The initial Next Generation Development Plan, unless otherwise agreed on by the Parties, will be agreed by the Parties no later than [***] months after Next Generation Option Exercise.

1.133 “**Next Generation Licensed Compound**” shall mean [***].

1.134 “**Next Generation Option**” shall have the meaning given in Section 2.9.

1.135 “**Next Generation Option Exercise**” shall have the meaning given in Section 2.9.

1.136 “**Non-Arbitral Subject Matter**” shall have the meaning given in Section 15.3.

1.137 “**Offer Notice**” shall have the meaning given in Section 2.13.

1.138 “**Original ADC Added Trials**” shall have the meaning provided in Section 4.2(b).

1.139 “**Original ADC Licensed Product**” shall mean [***].

1.140 “**Original ADC Licensed Product Development Budget**” shall have the meaning as set out in Section 1.141.

1.141 “**Original ADC Licensed Product Development Plan**” shall mean the written plan, as amended from time to time in accordance with the terms of this

Agreement, describing (i) the Development strategy for the Licensed Compound and Original ADC Licensed Products in the Territory and (ii) the material pre-clinical studies, Clinical Trials and regulatory activities proposed to be performed with respect to the Original ADC Licensed Products (iii) the planned Third Party contract research organisations for the Development activities; as well as (iv) the associated budget regarding the Development activities, including but not limited to the Development Costs, such as the costs for the Development activities performed by Licensee, its Affiliates or its subcontractors as well as the Duality Costs (“**Original ADC Licensed Product Development Budget**”). The preliminary Original ADC Licensed Product Development Plan together with the preliminary Original ADC Licensed Product Development Budget is attached hereto as **Schedule 1.141**.

1.142 “**Party**” shall mean Licensee or Duality individually, and “**Parties**” shall mean Licensee and Duality collectively.

1.143 “**Patents**” shall mean (a) patent applications filed in the applicable jurisdiction; (b) all patents, including supplemental protection certificates, that have issued or in the future issue from any of the foregoing, including utility models, design patents and certificates of invention; and (c) all divisionals, continuations, continuations-in-part, reissues, re-examination certificates, renewals, extensions or additions to any such patents and patent applications (as applicable).

1.144 “**Pharmacovigilance Agreement**” shall have the meaning provided in Section 5.6(c).

1.145 “**Phase I Clinical Trial**” shall mean a human clinical trial of a product, the principal purpose of which explores the optimal dose and is a determination of initial tolerance or safety of such product in healthy volunteers or the target patient population, as described in 21 CFR 312.21(a) (as amended or any replacement thereof), or a similar clinical trial prescribed by the Regulatory Authority in a country other than the United States.

1.146 “**Phase II Clinical Trial**” shall mean a human clinical trial of a product, the principal purpose of which is a determination of safety and efficacy in the target patient population, (i.e. “proof of concept”), as described in 21 C.F.R. 312.21(b) (as amended or any replacement thereof), or a similar clinical trial prescribed by the Regulatory Authority in a country other than the United States.

1.147 “**Phase III Clinical Trial**” shall mean a human clinical trial of a product, the design of which is acknowledged by the FDA to be sufficient for such clinical trial to satisfy the requirements of 21 C.F.R. 312.21(c) (as amended or any replacement thereof), or a similar human clinical trial prescribed by the Regulatory Authority in a country other than the United States, the design of which is acknowledged by such Regulatory Authority to be sufficient for such clinical trial to satisfy the requirements of a pivotal efficacy and safety clinical trial.

1.148 “**Planned Trials**” shall have the meaning given in Section 4.2(b).

1.149 “**Pre-clinical Proof-of-Concept**” shall mean that the Next Generation Licensed Compound has successfully met the criteria as set out in **Schedule 1.149**, or as amended by mutual agreement of the Parties.

1.150 “**Pricing and Reimbursement Approval**” shall mean, in any country where a Regulatory Authority authorizes reimbursement for, or approves or determines

pricing or level of reimbursement for, pharmaceutical products, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization and/or pricing approval or determination (as the case may be).

1.151 “**Product Marks**” shall have the meaning provided in Section 7.5.

1.152 “**Project Manager**” shall have the meaning provided in Section 3.10.

1.153 “**Proposed Publication**” shall have the meaning provided in Section 10.5(a).

1.154 “**Publication**” shall have the meaning provided in Section 10.5.

1.155 “**Receiving Party**” shall have the meaning provided in Section 10.1.

1.156 “**Reduced Royalty Rates**” shall mean the reduced royalty rates for the [***] and [***] specified in tables 3 and 4 in Section 8.6.

1.157 “**Registrational Trial**” shall mean, with respect to a product, a human clinical trial (regardless of whether such clinical trial is referred to as a “Phase II Clinical Trial”, “Phase IIb Clinical Trial”, “Phase II/III Clinical Trial”, “Phase IIb/III Clinical Trial” or “Phase III Clinical Trial”) for such product, the results of which, together with prior information concerning such product, are determined by the sponsor to be intended to be sufficient to establish that such product is safe and effective for its intended Indication to support the filing of an MAA. [***]

1.158 “**Regulatory Approval**” shall mean any and all approvals, licenses, permits, registrations or authorizations of or from any Regulatory Authority that are necessary to market (including Marketing Authorization) and sell a pharmaceutical product in any country, region or other jurisdiction. For clarity, unless it is required by the Applicable Law to initiate marketing and selling of a product in a particular country, Regulatory Approval shall not include Pricing and Reimbursement Approval.

1.159 “**Regulatory Authority**” shall mean with respect to a country, any national, federal, supranational, state or local regulatory agency, council, department, bureau or other governmental or regulatory authority having the administrative authority to regulate the development or marketing of pharmaceutical products in any country, region or jurisdiction. including the Regulatory Approvals.

1.160 [***]

1.161 “**Regulatory Materials**” shall mean, with respect to a product, regulatory applications (including MAA) and all applications, filings, submissions, notifications, materials, communications, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority in order to Develop, Manufacture, market, sell or otherwise Commercialize such product in a particular country, region or jurisdiction.

1.162 “**Remedial Action**” shall have the meaning provided in Section 5.7.

1.163 “**Retained Territory**” shall mean Mainland China, Hong Kong Special Administrative Region, and Macau Special Administrative Region.

1.164 “**Review Period**” shall have the meaning provided in Section 10.5(a).

1.165 "[***]" shall have the meaning provided in Section 2.13.

1.166 "[***]" shall have the meaning provided in Section 8.8(d).

1.167 "**Royalty Term**" shall have the meaning provided in Section 8.7.

1.168 "**Rules**" shall have the meaning provided in Section 15.1.

1.169 "**SEC**" shall have the meaning provided in Section 10.4(a)(i).

1.170 "**Selling Party**" shall have the meaning as provided in Section 1.128.

1.171 "**Separate**" shall mean, [***].

1.172 "**Solely Owned Collaboration IP**" shall mean Duality Solely Owned Collaboration IP and Licensee Solely Owned Collaboration IP, as applicable.

1.173 "**Solely Owned Collaboration Patents**" shall mean Duality Solely Owned Collaboration Patents and Licensee Solely Owned Collaboration Patents, as applicable.

1.174 "**Sublicense**" shall mean a license, sublicense, covenant not to sue or other rights granted by Licensee to a Third Party under the rights it receives from Duality in accordance with Section 2.2, to Develop, Manufacture, Commercialize or otherwise exploit a Licensed Compound or a Licensed Product, and/or after Next Generation Option Exercise, the Next Generation Licensed Compound or Next Generation ADC Licensed Products, but excluding any grant of rights to or agreement with (a) any Third Party acting as a service provider or subcontractor for such Party or its Affiliates, or (b) any Third Party wholesaler, distributor, or the like.

1.175 "**Sublicensee**" shall mean a Third Party that is receiving rights under a Sublicense.

1.176 "**Successful Completion**" shall mean, [***].

1.177 "**Target**" shall mean, with regard to an Antibody or ADC and a biological target in question, that such Antibody or ADC demonstrates meaningful binding activity to such biological target and "**Targeting**" shall be construed accordingly.

1.178 "**Tax Withholdings**" shall have the meaning provided in Section 9.4(b).

1.179 "**Term**" shall have the meaning provided in Section 13.1.

1.180 "**Territory**" shall mean worldwide except the Retained Territory. For clarity, Territory shall include Taiwan.

1.181 "**Third Party**" shall mean any entity other than Licensee and its Affiliates and Duality and its Affiliates.

1.182 "**Third Party Agreements**" shall have the meaning provided in Section 4.4(c).

1.183 "**Third Party Claims**" shall have the meaning provided in Section 14.1.

1.184 “**Trop2**” shall mean (a) Trophoblast cell-surface antigen 2, and (b) any naturally occurring variants thereof, in each case including any isoforms, polymorphisms, variants, and truncated forms, and in each case to the extent such variant, isoform, polymorphism, variant and truncated form are produced from an allele of the same TACSTD2 gene.

1.185 “**UNCITRAL**” shall have the meaning given in Section 15.2.

1.186 “**United States**” or “**U.S.**” shall mean the United States of America, including its territories and possessions as recognized by the United Nations from time to time, but in all cases including, for clarity, Puerto Rico.

1.187 “**Updated Disclosure Schedule**” shall have the meaning provided in Section 11.8.

1.188 “**US\$**” or “**U.S. Dollars**” shall mean U.S. dollars, the lawful currency of the U.S.

1.189 “**Upfront Payment**” shall have the meaning provided in Section 8.1.

1.190 “**Valid Claim**” shall mean [***].

1.191 “**WCB**” shall mean the working cell bank.

1.192 “**Wind-Down or Transfer Plan**” shall mean a plan for the wind-down or transfer of any ongoing Development, Manufacture and Commercialization (if any) activities of Licensee with respect to the Licensed Products for which the license grant in Section 2.1 has been terminated and the transfer of relevant Licensed Products, as applicable.

1.193 “[***] **Agreements**” shall mean the [***] Cell Line Agreement as well as the following agreements: [***].

1.194 “[***] **Cell Line Agreement**” shall mean [***].

Article 2 LICENSE

2.1 License Grant.

(a) **Territory License Grant.** Subject to the terms and conditions of this Agreement (including Duality’s retained rights in Section 2.4), Duality hereby grants and shall procure its Affiliates grant to Licensee and its Affiliates, during the Term, an exclusive (even as to Duality and its Affiliates), royalty-bearing license, with the right to sublicense through multiple tiers (in accordance with Section 2.2), under Duality Licensed IP to Develop, have Developed, Manufacture, have Manufactured, use, sell, offer for sale, import and otherwise Commercialize or have Commercialized or exploit the Licensed Compound or after Next Generation Option Exercise, the Next Generation Licensed Compound, and the Licensed Products in the Field in the Territory.

(b) **Retained Territory License Grant.** Subject to the terms and conditions of this Agreement (including Duality's retained rights in Section 2.4), Duality hereby grants to Licensee a sole license under Duality Licensed IP to Develop, have Developed, Manufacture or have Manufactured the Licensed Compound or after Next Generation Option Exercise, the Next Generation Licensed Compound, and the Licensed Products in the Retained Territory solely for the purpose of Developing, Manufacturing and Commercializing the Licensed Products in the Field in the Territory.

2.2. Sublicense Rights.

(a) **Right to Sublicense.** Subject to the terms and conditions of this Agreement, Licensee and its Affiliates shall have the right to grant Sublicenses through multiple tiers under Duality Licensed IP (including Duality In-Licensed IP), in each respect to (i) any Affiliate, or (ii) to any Third Party.

(b) **Sublicense Terms.** [***]

(c) **Licensee's Responsibility.** Licensee shall use Commercially Reasonable Efforts to ensure that the performance by any of its Affiliates, Sublicensees and subcontractors hereunder is in accordance with the applicable terms of this Agreement. With respect to a patent challenge by the Sublicensee against any Duality Patents, if Licensee fails to cause such Sublicensee to cease such violation within a reasonable period of time, Licensee shall, in so far as it is not prohibited under the Applicable Laws, terminate the sublicense agreement.

2.3 Negative Covenants. In so far as it is not prohibited under the Applicable Laws, Licensee hereby covenants on a country-by-country basis not to, and not to permit or cause any Affiliate [***]. Notwithstanding the foregoing, this Section 2.3 shall in no way restrict [***], its Affiliates, its Sublicensees or their CMOs and other authorized Third Party under this Agreement from undertaking any research, Development, Manufacturing, Commercialization, or other exploitation or engaging in any activities involving [***] that anyone not subject to this Agreement may legally undertake before the Effective Date and during the Term in the Territory and elsewhere. [***]. [***]

2.4 No Implied Licenses; Retained Rights. No right or license under any Patents or Know-How of either Party is granted or shall be granted by implication. All such rights or licenses are or shall be granted only as expressly provided in the terms of this Agreement. Duality hereby expressly reserves all rights not expressly licensed to Licensee in Section 2.1, including (i) all rights under the Duality Licensed IP with respect to the Licensed Compound and Original ADC Licensed Products, or after Next Generation Option Exercise, the Next Generation Licensed Compound and Next Generation ADC Licensed Product in the Retained Territory, subject to Licensee's co-exclusive license as set forth in Section 2.1(b), (ii) all rights under the Duality Licensed IP to exercise its rights or perform its obligations under this Agreement, and (iii) all rights under the Duality Licensed IP to conduct Development activities in the Territory for the sole purpose of Developing or Commercializing the Original ADC Licensed Products or Next Generation ADC Licensed Product in the Field in the Retained Territory; *provided that* any such Development activities in the Territory in relation to the Original ADC Licensed Product, or Next Generation ADC Licensed Product and Licensed Compound or Next Generation Licensed Compound shall be undertaken for Duality by Licensee or its Affiliates, or Sublicensees or Licensee's designated subcontractors.

2.5 License to Duality. Licensee hereby grants to Duality a non-exclusive, non-transferrable, non-sublicensable (unless a sublicense was consented to by Licensee in

writing and is in compliance with the license terms set out in Section 2.2(b), which would apply *mutatis mutandis*), royalty-free license under the Licensee Licensed IP, during the Term of this Agreement, solely to (i) perform, either itself, through its Affiliates, or through subcontractors, its obligations under this Agreement, including its Manufacturing and supply obligations under Sections 6.1, 6.4 and 6.5, and (ii) limited to the Field and the Retained Territory, to Develop, Manufacture or have Manufactured, or Commercialize the Licensed Compound or Original ADC Licensed Products or after Next Generation Option Exercise, the Next Generation Licensed Compound and Next Generation ADC Licensed Product. Duality shall use Commercially Reasonable Efforts to ensure that the performance by any of its Affiliates, sublicensees or subcontractors hereunder is in accordance with the applicable terms of this Agreement. With respect to a patent challenge by a (sub)licensee against any Licensee Patents, if Duality fails to cause such (sub)licensee to cease such violation within a reasonable period of time, Duality shall, in so far as it is not prohibited under the Applicable Laws, terminate such (sub)license agreement. Duality shall be responsible for any actions of its Affiliates, sublicensees and subcontractors who act on behalf of Duality to perform activities assigned to Duality (for or on behalf of Licensee) pursuant to this Agreement, to the same extent as if such actions had been taken by Duality itself, and Licensee shall have the right to proceed directly against Duality without any obligation to first proceed against such Affiliate, sublicensee and subcontractor.

2.6 Know-How and Technology Transfer.

Within [***] days of the Effective Date, Duality shall, at its cost and expense, provide to Licensee [***] the documents embodying all Duality Know-How, in original form and English language certified translations, (including but not limited to CMC documentation to the extent available to Duality or any of its Affiliates as of the Effective Date) Controlled by Duality or any of its Affiliates as of the Effective Date, including but not limited all Know-How that has been obtained by Duality under the [***] Agreement and the [***] Agreements as of the Effective Date, [***]. A description of such documents for the initial Know-How Transfer as of the Effective Date is attached as **Schedule 2.6** hereto.

Thereafter, Duality shall promptly (and in any event no later than [***] from the existence of such Know-How) inform Licensee of the existence of any additional Duality Know-How that becomes Controlled by Duality after the Effective Date and during the Term, including Know-How agreed to be provided under or obtained under the [***] Agreement and the [***] Agreements. The Parties shall discuss the timing and means of the transfer of additional Duality Know-How.

Upon Licensee's request, Duality shall provide, and shall cause Third Parties (including but not limited to the [***] and [***] entities that are party to the [***] Agreement or the [***] Agreements, as applicable) to provide (as applicable), electronic copies of such additional Duality Know-How (including CMC-Materials) and disclose, make available and support the onsite implementation of the Manufacturing process technology transfer to Licensee or Licensee's Third Party manufacturer in accordance with Section 6.2 below, and at no additional cost to Licensee beyond the costs set out in Section 6.2.

2.7 Non-Competition.

[***]

2.8 Duality Immune Agonist ADC Product. [*]**

2.9 Next Generation Licensed Compound or Next Generation ADC Licensed Product.

(a) Subject to the terms and conditions of this Agreement, Duality hereby grants to Licensee an exclusive option (for clarity, this option grant is fully paid-up by the payments made under this Agreement, no additional consideration is needed for this exclusive option) to obtain an exclusive license to Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized or otherwise exploit in the Territory, any Next Generation Licensed Compound and/or Next Generation ADC Licensed Product, which may be exercised by Licensee in accordance with Section 2.9(b) (“**Next Generation Option**”).

(b) The Next Generation Option may be exercised by Licensee upon written notice to Duality at any time until [***] months after successful Pre-clinical Proof-of-Concept and full disclosure by Duality of the complete Next Generation Data Package (“**Next Generation Option Exercise**”). Licensee shall be entitled to request additional data and information required for due diligence to make an informed decision in relation to the exercise of this Next Generation Option. Licensee shall complete its due diligence on the Next Generation Licensed Compound and Next Generation ADC Licensed Product within [***] months after delivery of the complete Next Generation Data Package by Duality to Licensee. For clarity, the Next Generation Option shall expire if the Next Generation Option Exercise does not occur within such [***] month period.

(c) After the Next Generation Option Exercise with respect to a Next Generation Licensed Compound, any other Next Generation Licensed Compound (other than the one with respect to which Licensee exercised the Next Generation Option) would automatically qualify as Duality Competing Product and fall under the non-compete obligation of Duality in Section 2.7. If Licensee chooses not to exercise the Next Generation Option, any Next Generation Licensed Compound or Next Generation ADC Licensed Product (including the one with respect to which Licensee declined to exercise the Next Generation Option) would automatically become a Duality Competing Product and fall under the non-compete obligation of Duality in Section 2.7.

(d) For the avoidance of doubt, the Next Generation Option Exercise will not trigger any additional payments, such as upfront or milestone payments, other than those set forth in Section 8.3, 8.5 and 8.6 (ii).

2.10 [***]

2.11 [***]

2.12 **Third Party Licenses.** [***]

2.13 [***]

Article 3 GOVERNANCE

3.1 **General.** The Parties have already created a governance structure and committees for the implementation of the HER2 License and Collaboration Agreement dated March 31, 2023 (“**HER2 Agreement**”), such governance structure the “**HER2 Governance Structure**”). Unless otherwise agreed by the Parties in writing, the Parties agree that the HER2 Governance Structure

shall apply to this Agreement, unless the HER2 Agreement is terminated by the Parties, or unless otherwise agreed by the Parties.

3.2 Joint Steering Committee. The Parties have established a JSC comprised of an equal number of representatives from each Party to approve, plan, coordinate, integrate monitor and oversee the Development, Manufacture and regulatory activities of the Parties' in the Territory with respect to the Original ADC Licensed Product and/or, after Next Generation Option Exercise, the Next Generation Licensed Compound and Next Generation ADC Licensed Product and facilitate information exchange between the Parties under this Agreement. The JSC, as may be conducted through the applicable Subcommittee, shall in particular:

- (a) review, discuss and coordinate the overall strategy for the Development of the Original ADC Licensed Products and/or, after Next Generation Option Exercise, the Next Generation Licensed Compound and Next Generation ADC Licensed Product in the Territory;
- (b) discuss the status of the Development of the Next Generation Licensed Compound (before and after Next Generation Option Exercise);
- (c) review, discuss and approve any proposed amendments or revisions to the Development Plan(s) of the Original ADC Licensed Products and/or, after Next Generation Option Exercise, the Next Generation Licensed Compound and Next Generation ADC Licensed Product including all related budgets of the Development activities;
- (d) review, discuss and approve any study protocols relating to the Development Plan(s) (and any amendments thereto) of the Original ADC Licensed Products and/or, after Next Generation Option Exercise, the Next Generation Licensed Compound and Next Generation ADC Licensed Product;
- (e) review, discuss and serve as a forum for the sharing of information between the Parties regarding the operation of any Development activities of the Original ADC Licensed Products in the Territory and in the Retained Territory and/or, after Next Generation Option Exercise, the Next Generation Licensed Compound and Next Generation ADC Licensed Product;
- (f) oversee and coordinate the on-going disclosure, sharing and/or transfer of new Collaboration IP generated in or related to the Development of the Original ADC Licensed Products and/or, after Next Generation Option Exercise, the Next Generation Licensed Compound and the Next Generation ADC Licensed Product in the Territory;
- (g) review and discuss any matters relating to the Regulatory Approvals and Regulatory Materials to be submitted to any Regulatory Authority in respect of the Original ADC Licensed Products in the Territory and matters relating to attending regulatory meetings or consultations with Regulatory Authorities in respect of the Original ADC Licensed Products and/or, after Next Generation Option Exercise, the Next Generation Licensed Compound and the Next Generation ADC Licensed Product in the Territory;
- (h) coordinate supply of Original ADC Licensed Products and/or, after Next Generation Option Exercise, the Next Generation Licensed Compound and Next Generation ADC Licensed Product in accordance with Article 6;
- (i) review and discuss the clinical protocol of and Duality's potential participation in any Global Trial sponsored by Licensee or any of its Affiliates and Sublicensees, or Original ADC Added Trials; and

(j) perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or as determined by the Parties in writing.

3.3 Subcommittees.

From time to time during the Term, the JSC may establish and disband one or more subcommittee(s) (each, a “**Subcommittee**”) to oversee particular activities of the Parties, and the JSC may assign to such subcommittee(s) duties or tasks independent of the duties of the JSC, or delegate part of such duties of the JSC to such subcommittee(s) as it deems necessary and appropriate.

(a) **Joint IP Committee.** Unless already existing under the HER2 Governance Structure, no later than [***] days after the Effective Date (unless otherwise agreed by the Parties), the JSC shall establish an intellectual property committee (the “**Joint IP Committee**” or “**JIPC**”) led by Licensee and comprised of an equal number of representatives from each Party. The JIPC shall provide a forum for discussion of the patenting strategies of the Licensed Compound, the Original ADC Licensed Products and/or, after Next Generation Option Exercise, the Next Generation Licensed Compound and Next Generation ADC Licensed Product, and coordinate the Parties’ efforts in accordance with the provisions set forth in Article 12 and other matters related to the prosecution and maintenance of intellectual property rights hereunder, including submissions to and addressing notices from Regulatory Authorities that relate to regulatory-patent linkage procedures and proceedings. The JSC shall determine the desired membership of the JIPC and once formed, Licensee’s committee members shall determine the time, place and procedure of meetings. [***]

(b) **Joint Development Committee.** Unless already existing under the HER2 Governance Structure, no later than [***] days after the Effective Date, the JSC shall establish a joint development committee (the “**Joint Development Committee**” or “**JDC**”) led by Licensee and comprised of an equal number of representatives from each Party. The JDC shall (i) oversee the implementation and progress of the Development Plan in the Territory, (ii) discuss and propose to the JSC for approval any amendments to the Development Plan, (iii) oversee any Global Trials.

3.4 Composition; Meetings. If not otherwise agreed for the HER2 Governance Structure, the JSC and each Subcommittee (each, a “**Committee**”) shall be composed of [***] representatives from each Party (or such other equal number of representatives of each of Licensee and Duality as the JSC may determine), and each Party shall notify the other Party of its initial JSC representatives within [***] days after the Effective Date. Each Party shall designate a representative to be the co-chairperson of the JSC and Licensee shall designate a representative to chair each Subcommittee led by it, in each case, who shall schedule meetings, prepare meeting agendas and meeting minutes and follow up on action items. Each Party may request and convene a Committee meeting and propose agenda therefor at any time. With respect to the JSC, these responsibilities will alternate between the Parties or each co-chairperson, as applicable, with Licensee’s co-chairperson taking the responsibility for the first meeting of the JSC. Each Party may change its representatives to the JSC (or any Subcommittee) from time to time in its sole discretion, effective upon notice to the other Party of such change. Each Party’s representatives in each Committee shall possess appropriate experience with respect to the issues falling within the functions of such Committee and requisite seniority within such Party’s organization, and shall have the authority to make decisions on behalf of the Party they represent.

3.5 Non-Member Attendance. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend a meeting of any Committee

(in a non-voting capacity) in the event that the planned agenda for such Committee meeting would require such participants' expertise; provided that if either Party intends to have any Third Party (including any consultant or counsel) attend such a meeting, such Party shall provide prior written notice to the other Party, shall obtain approval from such other Party for such Third Party to attend (which shall not be unreasonably withheld, conditioned or delayed by the notified Party), and shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

3.6 Decision-Making. The representatives of each Party will have [***] vote at each Committee on all matters brought before such Committee. The Committees may not take any action or decide any matter except at a meeting attended by [***] representing each Party and with unanimous consent.

(a) **JSC Decisions.** Except where consent or approval on any matter by a Party is expressly required herein, if after reasonable discussion and good faith consideration of each Party's view on any matter within the decision-making authority of the JSC (including those matters referred to the JSC by any Subcommittee), the representatives of the Parties on the JSC cannot reach an agreement as to such matter within [***] Days after such matter was brought to the JSC for resolution or after such matter has been referred to the JSC, such disagreement shall be referred to the Chief Executive Officer of Duality and Chief Executive Officer of Licensee (collectively, the "**Executive Officers**") for resolution. If the Executive Officers cannot resolve such matter within [***] days (or such other timeframe as the JSC may request in consideration of the urgency of such referred matter) after such matter has been referred to them, then:

(i) [***] shall be entitled to make final decisions with respect to:

(A) [***]

(B) [***]

(C) [***]

(D) [***]; and

(ii) [***] shall be entitled to make final decisions on the [***]:

[***]; and

(iii) with respect [***]:

(A) [***] will have final decision-making authority with respect to matters relating to [***]; and

(B) [***] will have final decision-making authority with respect to matters relating to [***].

(b) **JIPC Decisions.** Except where consent or approval on any matter by a Party is expressly required herein, if after reasonable discussion and good faith consideration of each Party's view on any matter within the decision-making authority of the JIPC, together with the assistance of each Party's outside intellectual property counsel, the representatives of the Parties on the JIPC cannot reach an agreement as to such matter within [***] Days after such matter was brought to the JIPC for resolution or

after such matter has been referred to the JIPC, such matter shall be escalated to the JSC by either Party.

(c) **JDC Decisions.** Except where consent or approval on any matter by a Party is expressly required herein, if after reasonable discussion and good faith consideration of each Party's view on any matter within the decision-making authority of the JDC, the representatives of the Parties on the JDC cannot reach an agreement as to such matter within [***] Days after such matter was brought to the JDC for resolution or after such matter has been referred to the JDC, such disagreement shall be escalated to the JSC by either Party.

(d) **Deadlock Resolution.** In case of a deadlock with respect to the decision-making process of the JSC, Section 15.1 shall apply.

3.7 Limitations on Authority. The JSC shall have only such powers as are expressly assigned to it in this Agreement, and such powers shall be subject to the terms and conditions of this Agreement. Without limiting the generality of the foregoing, the JSC shall not have the power to amend this Agreement, shall not have power in relation to [***] or the [***], and no decision of the JSC may be in contravention of any terms and conditions of this Agreement. For clarity, the JSC shall have no decision-making authority regarding any Development, Manufacturing, Commercialization or other activity in the Retained Territory save as contemplated by Section 3.6(a) or otherwise expressly provided in this Agreement.

3.8 Meetings. The JSC will hold a meeting every [***] months until the Development Phase ends, and afterwards every [***] months, or as otherwise determined by the JSC. Such meetings may be in person, via videoconference, or via teleconference. The location of in-person meetings will be determined by the Parties. At least [***] Days prior to each JSC meeting, each Party shall provide written notice to the other Party of agenda items proposed by such Party for discussion at such meeting, together with appropriate information related thereto. Reasonably detailed written minutes will be kept for all JSC meetings. Meeting minutes will be prepared [***] and sent to each member of the JSC for review and approval within [***] Days after the meeting. Minutes will be deemed approved unless a member of the JSC objects to the accuracy of such minutes within [***] Days of receipt. In the event of any such objection that is not resolved by mutual agreement of the Parties, such minutes will be amended to reflect such unresolved dispute.

3.9 Discontinuation of JSC. The JSC shall continue to exist until the Parties mutually agree to disband the JSC. Once the JSC is disbanded, the JSC shall have no further obligations under this Agreement and, thereafter, the Alliance Managers shall be the points of contact for the exchange of information under this Agreement, and the Parties shall reach decision directly on matters that are subject to the decision of the JSC as set forth in Section 3.1.

3.10 Project and Alliance Managers. Each Party shall appoint an individual, who is an employee of such Party, to act as a project manager (the "**Project Manager**") who shall be responsible for implementing and coordinating activities and facilitating the exchange of information between the Parties. Each Party shall appoint an individual, who is an employee of such Party, to act as its alliance manager under this Agreement within [***] Days after the Effective Date (the "**Alliance Manager**"). [***] The Project Managers shall: (a) serve as the primary points of contact between the Parties for the purpose of providing the other Party with information on the progress of a Party's activities under this Agreement; (b) be responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties. The Alliance Managers shall: (a) serve as the primary points of contact between the Parties for any issues arising under this Agreement; (b) facilitate the prompt resolution of any disputes; and (c) attend JSC and Subcommittee meetings (in each case,

as a non-voting participant); provided that the Alliance Managers shall not count toward the number of representatives that each Party may have on each such Committee. An Alliance Manager may also bring any matter to the attention of the JSC, if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party may replace its Project Manager and Alliance Manager at any time upon written notice to the other Party.

Article 4 DEVELOPMENT

4.1 Overview; Diligence.

(a) Except as expressly provided herein with respect to the Planned Trials, Original ADC Added Trials (as applicable) or after Next Generation Option Exercise, the Next Generation Added Trials, Licensee (itself and through its Affiliates and their respective Sublicensees) shall be responsible, at its own expense, for the Development of the Original ADC Licensed Products or after the Next Generation Option Exercise, Next Generation ADC Licensed Product in the Field in the Territory under the oversight of JSC. Without limiting the generality of the foregoing, Licensee shall, in accordance with the Development Plan (i) use Commercially Reasonable Efforts to Develop and seek Regulatory Approval for [***] in the Field in [***], and (ii) perform the Development activities assigned to it under the Development Plan(s) in compliance with Applicable Laws (including GXPs), with reasonable due care and in conformity with current generally accepted industry standards and procedures. Licensee shall use Commercially Reasonable Efforts to adhere to the timelines set forth in the Development Plan. For the avoidance of doubt, Licensee shall have fulfilled its diligence obligation under Section 4.1(a) (i) if it has used Commercially Reasonable Efforts to develop and seek Regulatory Approval for either the Original ADC Licensed Products or a Next Generation ADC Licensed Product in [***]. Licensee is not obliged to develop and/or seek Regulatory Approval for both the Original ADC Licensed Products and the Next Generation ADC Licensed Product. For the avoidance of doubt, as regards the Clinical Trials in the Retained Territory, unless otherwise agreed under this Agreement, Duality shall be solely responsible at its own expenses, for the Development of the Original ADC Licensed Products and the Next Generation ADC Licensed Product in the Retained Territory.

(b) Without limiting the foregoing, Licensee shall use Commercially Reasonable Efforts to (i) make all regulatory submissions to the applicable Regulatory Authorities within the Territory in respect of the Original ADC Licensed Product, or after Next Generation Option Exercise, the Next Generation ADC Licensed Product; and (ii) obtain Regulatory Approval for Original ADC Licensed Products, or after Next Generation Option Exercise, the Next Generation ADC Licensed Product; in the Territory, in each case of (i) and (ii) in accordance with the Development Plan.

4.2 Development of Original ADC Licensed Product.

(a) **Development Plan.** The initial Original ADC Licensed Product Development Plan, which sets forth the scope, timelines and responsibilities of each Party of the Development activities to be conducted by or on behalf of Licensee in order to obtain Regulatory Approvals for the Original ADC Licensed Products in the Territory is attached hereto as Schedule 1.141. The Original ADC Licensed Product Development Plan shall in particular set out the Original ADC Licensed Product Development Budget allocated to these Development activities. From time to time during the Term, either Party may propose written amendments and updates to the then-current Original ADC Licensed Product Development Plan, and shall submit such amendments and updates to the JSC for review

and approval. Any amendment of the Original ADC Licensed Product Development Plan and the Original ADC Licensed Product Development Budget shall become effective only upon the approval of the JSC.

(b) **Clinical Trials to Be Conducted by Duality in the Territory.** As of the Effective Date and as set forth in the Original ADC Licensed Product Development Plan, the Parties have agreed that Duality will conduct, at its own cost and expense, the Clinical Trials in the Territory until the [***] in accordance with the Development Plan and in compliance with all Applicable Laws (together, “**Planned Trials**”); [***].

(c) **Global Trials.** [***]

[***]

(d) **Phase [***] Clinical Trial.**

[***]

4.3 Development of Next Generation ADC Licensed Product.

(a) **General.** [***]

(b) **No Next Generation Option Exercise.** [***]

(c) **After Next Generation Option Exercise.**

[***]

4.4 Duality Development Activities.

(a) Where Duality is responsible for conducting Development activities under this Agreement in the Territory, including but not limited to conducting the Planned Trials, and if applicable, the Original ADC Added Trials and, after the Next Generation Option Exercise the Development of the Next Generation Licensed Compound and Next Generation ADC Licensed Product in accordance with Section 4.3, and, if applicable the Next Generation Added Trials (“**Duality Development Activities**”), [***]

(b) Any intended delegation of the Duality Development Activities or any part thereof to a subcontractor shall be communicated to Licensee via the JDC in advance and shall be reflected in the initial (and updated) Development Plan, already listing the subcontractors that Duality intends to involve. The delegation to any such subcontractor requires Licensee’s prior written consent which shall not be unreasonably withheld, conditioned or delayed; provided that Licensee shall be deemed to have given its consent if Licensee’s Project Manager and Licensee’s Alliance Manager, who were informed about the identity of the subcontractor via the JDC, do not respond within [***] Days after both Licensee’s Project Manager’s and Licensee’s Alliance Manager’s receipt of written notice from Duality; provided further that such notice contains sufficient information for Licensee to make an informed decision. . A response by Licensee can also be a request for further information or comments.

(c) Duality shall, upon request by Licensee, (i) keep Licensee copied on the main communications regarding the contract negotiations with the subcontractor and Licensee may decide, in its own discretion, to participate in the contract negotiations with the subcontractor; provided that Duality does not need to reschedule negotiations because

of Licensee's unavailability, and (ii) provide Licensee with a copy of any draft subcontractor agreement proposed to it with respect to the Duality Development Activities or Manufacture activities (such subcontractor agreements the "**Third Party Agreements**"), including but not limited to agreements with CROs. Such Third Party Agreements shall be in the English language. Any such Third Party Agreement will only be signed after obtaining a written consent of Licensee which shall not be unreasonably withheld, conditioned or delayed; provided that Licensee shall be deemed to have given its consent if Licensee's Project Manager and Licensee's Alliance Manager were copied on the main communications regarding the contract negotiations, given the opportunity to participate in the contract negotiation, and regularly updated on the progress of the negotiations (together with the draft Third Party Agreement) and do not respond within [***] Days after both Licensee's Project Manager's and Licensee's Alliance Manager's receipt of a full copy of such draft Third Party Agreements and the written notice from Duality. A response by Licensee can also be a request for further information (i.e. not information that has been provided) or comments.

4.5 Development Records. Each Party shall maintain or cause to be maintained complete, current and accurate records of all activities conducted by or on behalf of it pursuant to the Development Plan(s), and all Know-How and other information resulting from such activities. For Duality this shall also apply to any Development activities with respect to the Next Generation Licensed Compound or Next Generation ADC Licensed Product. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes. Each Party shall, and shall ensure that its Affiliates, their Sublicensees and subcontractors will, document all non-clinical studies and Clinical Trials in formal written study records in accordance with all Applicable Laws, including applicable national and international guidelines such as ICH, GCLP, GCP and GLP. To the extent permitted by the Applicable Laws, each Party shall have the right to review and copy such records of the other Party at reasonable times and to obtain access to review the original to the extent necessary or useful for regulatory, patent or other reasonable purposes for the purpose of fulfilling its obligations under this Agreement upon reasonable notice to such other Party and at a time and location mutually acceptable to the Parties.

4.6 Development Reports. Each Party shall keep the other Party reasonably and timely informed of the progress and results of its and its Affiliates', subcontractors' and Sublicensees'/(sub)licensees' work under the Development Plan(s) (including prompt reporting of available pre-clinical and clinical data). For Duality this shall also apply to any Development activities of Duality with respect to the Next Generation Licensed Compound or Next Generation ADC Licensed Product. Without limiting the generality of the foregoing, each Party shall provide the other Party with a written report no later than [***] days after the end of each Calendar Year setting forth in details the Development activities performed during such Calendar Year and the results thereof, and comparing such activities with the Development Plan(s) for such time period. Such reports prepared by each Party shall be provided at a level of detail reasonably sufficient to enable the other Party to determine the other Party's compliance with its obligations under this Agreement. At each JSC meeting, the Parties shall discuss the status, progress and results of the Development activities conducted by the Parties pursuant to this Agreement. Each Party shall promptly respond to the other Party's reasonable questions or requests for additional information relating to such Development activities. In the event that Duality is engaged by Licensee to conduct Duality Development Activities in the Territory, Duality shall send the Development report [***], setting forth in more detail the Duality Development Activities performed [***].

Article 5
REGULATORY

5.1 Overview of Conduct of Regulatory Activities.

(a) Licensee (itself and through its Affiliates and Sublicensees, as applicable) shall be responsible for all of the costs for all regulatory activities with respect to the Licensed Products in the Territory after the Effective Date. [***], Licensee (or its Affiliate or Sublicensees) shall be the sponsor and holder of all Regulatory Approvals for the Licensed Products in the Territory. For clarity, Licensee (or one of its Affiliates or their Sublicensees) shall always be the MAH of the Original ADC Licensed Products and/or, after Next Generation Option Exercise, the Next Generation Licensed Compound and Next Generation ADC Licensed Product in the Territory.

(b) Following [***] days after the Effective Date, Duality shall provide Licensee with one (1) electronic copy of the Regulatory Materials related to the Licensed Compound and Original ADC Licensed Products in the Territory existing and possessed by Duality as of the Effective Date. At any time during the Term, if Duality is the sponsor or holder of the Regulatory Materials and upon Licensees' written request, Duality shall provide Licensee with electronic copies of the Regulatory Materials related to the Licensed Compound or Original ADC Licensed Products and/or, after Next Generation Option Exercise, the Next Generation Licensed Compound and Next Generation ADC Licensed Products in the Territory received and possessed by Duality after the Effective Date promptly and in any event no later than [***] Days after such Regulatory Materials become available.

5.2 Regulatory Filing; Ownership.

(a) **Regulatory Filings.** Except with respect to regulatory filings related to the Planned Trials and Original ADC Added Trials (if any), for which Duality shall be responsible unless the Parties agree otherwise, (i) Licensee (and its Affiliates or Sublicensee, as applicable) shall lead and have sole control over preparing and submitting all regulatory filings related to the Licensed Compound and Original ADC Licensed Products and/or, after Next Generation Option Exercise, the Next Generation Licensed Compound and Next Generation ADC Licensed Product, including all applications for Regulatory Approval, in the Territory at Licensee's sole cost and expense, and (ii) Duality shall be responsible for the preparation and submission of any regulatory filings in the Retained Territory at Duality's sole cost and expense. With respect to regulatory filings for the Planned Trials or and the Original ADC Added Trials (if any) that are prepared by Duality, Duality shall submit all such regulatory filings to the JSC for its review and approval.

(b) **Ownership.** Other than any Regulatory Approvals or applications therefor that are related to the Planned Trials or Original ADC Added Trials (if any), for which Licensee has designated Duality to be the sponsor and with respect to which Section 5.4 applies, Licensee (or its Affiliates or Sublicensees, as applicable) shall own any and all Regulatory Approvals (and applications for Regulatory Approvals), and any other regulatory filings related to the Licensed Compound and Original ADC Licensed Products and/or, after Next Generation Option Exercise, the Next Generation Licensed Compound and Next Generation ADC Licensed Product in the Territory, including Data and data in the regulatory filings and Regulatory Materials, which shall be held in the name of Licensee or its designees.

(c) **English Translation.** To the extent that the original language is not English, Duality shall provide Licensee with a certified full English translation of all Regulatory Materials.

5.3 Interactions with Regulatory Authorities. Insofar as it relates to the Planned Trials and Original ADC Added Trials (if any) where Licensee has confirmed and consented in writing that Duality is the sponsor, Duality shall lead interactions with Regulatory Authorities in the Territory; provided that JSC shall have final decision making authority in relation to such interactions with Regulatory Authorities and Duality shall follow all instructions provided to it by the JSC in this regard and Duality shall provide Licensee with (i) access to or copies of all material written or electronic communication received by Duality or its Affiliates from any Regulatory Authorities in the Territory and in the Retained Territory (if applicable), and (ii) copies of all meeting minutes with any Regulatory Authorities in the Territory and in the Retained Territory (if applicable). In addition, Duality shall provide Licensee with written notice of any scheduled material meeting, conference, or discussion with a Regulatory Authority related to Regulatory Approvals related to the Planned Trials and Original ADC Added Trials (if any). Licensee (or its designee) shall have the right to (i) attend and participate in all such meetings with Regulatory Authorities related to the Planned Trials, Original ADC Added Trials (if any) and Next Generation Added Trials (if any), and all telephone conferences and preparation meetings of Duality or its Affiliates related to any such meeting, (ii) provide input on the regulatory filings in the Territory and in the Retained Territory (to the extent this impacts the position of Licensee in the Territory), and (iii) have final decision making authority in relation to any unsettled matter between the Parties with respect to regulatory filings in the Territory. Subject to the foregoing, Licensee (and/or its Affiliates, or Sublicensees as applicable) shall have the sole right to conduct all communications with Regulatory Authorities, including all meetings, conferences and discussions (including advisory committee meetings), with regard to the Licensed Compound and Original ADC Licensed Products and, after Next Generation Option Exercise, all Next Generation Licensed Compound and Next Generation ADC Licensed Products, in the Territory, including in respect of the Original ADC Added Trials where Licensee (or its Affiliates or Sublicensees, as applicable) is the sponsor (if any). Without limiting the foregoing, the Parties agree that they will collaborate with each other as necessary to ensure the successful progression of interactions with Regulatory Authorities with respect to all trials relating to the Licensed Compound and Original ADC Licensed Products, and/or after Next Generation Option Exercise, all Next Generation Licensed Compound and Next Generation ADC Licensed Product, in the Territory and in the Retained Territory (to the extent this impacts the position of Licensee in the Territory).

5.4 [***]. [***]. Duality shall transfer and assign, or shall cause the transfer or assignment, to Licensee or its designee (at Duality's cost and expense for Planned Trials and at Licensee's cost and expense for Original ADC Added Trials), Duality's, or any of its Affiliates', entire right, title, and interest in and to all IND and other Regulatory Approvals in the Territory, if any, and transfer all Regulatory Materials with respect to the Licensed Compound and Original ADC Licensed Products, and/or, after Next Generation Option Exercise, all Next Generation Licensed Compound and Next Generation ADC Licensed Product, in the Territory that are owned, controlled or possessed by Duality or any of its Affiliates, unless the Parties agree otherwise.

5.5 Replacement. At any time during the Term, Licensee may decide to replace Duality to be the sponsor of any Planned Trials and Original ADC Added Trials or Next Generation Added Trials (if any) in the Territory. Once Licensee informs Duality by written notice of its decision to replace Duality as the sponsor of any such Clinical Trials in the Territory, Duality shall within [***] days after receipt of such written notice from Licensee (a) transfer to Licensee all Regulatory Materials (including but not limited to the applicable IND, protocol and investigator's brochure) in connection with each of its ongoing Clinical Trials as of

the date of such notice and (b) use commercially reasonable efforts to facilitate Licensee's introduction to applicable CROs, study site(s) and investigator(s) in connection with each such Clinical Trial in order to assist Licensee in transferring such Clinical Trial to Licensee, in each case ((a) and (b)) in accordance with Applicable Law and accepted pharmaceutical industry norms and ethical practices. To the extent that the original language of the Regulatory Materials is not English, Duality shall provide a certified full English translation of all documents to Licensee. Licensee shall be responsible for all costs and expenses reasonably incurred by Duality in relation to or as a result of such replacement; provided that if the replacement was caused by a breach of the applicable terms of this Agreement, Applicable Laws or the GXP by Duality, the costs and expenses reasonably incurred by Licensee in relation to or as a result of such replacement shall be borne by Duality.

5.6 Data Access; Right of Reference; Access to Regulatory Materials; pharmacovigilance; audit.

(a) [***]

(b) [***]

(c) [***]

(d) Within [***] days of the Effective Date, the Parties shall enter into a pharmacovigilance agreement (the "**Pharmacovigilance Agreement**") regarding the Licensed Compound and Original ADC Licensed Products which shall set forth standard operating procedures governing the collection, investigation, reporting, and exchange of safety information sufficient to permit each Party to comply with its regulatory and other legal obligations within the applicable timeframes. After Next Generation Option Exercise, the Parties shall enter into a Pharmacovigilance Agreement regarding the Next Generation Licensed Compound and Next Generation ADC Licensed Product. In the event of any inconsistency between the terms of this Agreement and the Pharmacovigilance Agreement(s), the terms of this Agreement shall prevail and govern, except to the extent such conflicting terms relate directly to the pharmacovigilance/safety responsibilities of the Parties (including the exchange of safety data), in which case the terms of the Pharmacovigilance Agreement(s) shall prevail and govern. Prior to the Parties entering into the Pharmacovigilance Agreement, Duality is and shall continue to be the owner of the global safety database for the Original ADC Licensed Products. Unless otherwise agreed by the Parties in the Pharmacovigilance Agreement, the Pharmacovigilance Agreement can be amended at Licensee's request during the Term and as a preparation to the Commercialization, at least [***] months' ahead of the first MAA submission.

(e) At any time during the Term, upon reasonable prior notice, during regular business hours and under obligations of confidentiality, Licensee (or its designees) shall be entitled to audit (i) any of Duality's or its Affiliates', or any of their respective CROs' or CMOs' manufacturing sites; and (ii) any of Duality's, its Affiliates' clinical sites, as selected by Licensee in its sole discretion, to assess Duality's compliance with all GXPs and all matters arising under the Pharmacovigilance Agreement, in each case of the foregoing (i) and (ii), only in respect of any Clinical Trials run by Duality for Licensee in the Territory; provided that such audit shall not be conducted more than once in any given Calendar Year, unless it is a for-cause audit. If (a) such audit by Licensee identifies any material non-compliance by Duality (via its subcontractors) or its Affiliates (via its subcontractors) of the GXPs or the Pharmacovigilance Agreement in the Territory, and (b) such material non-compliance is confirmed to be an uncured material breach on the part of Duality pursuant to Section 13.3, then the provisions of Section 13.8 shall apply.

5.7 Remedial Actions. Each Party shall notify the other immediately, and promptly confirm such notice in writing, if it obtains information indicating that any Original ADC Licensed Product or Next Generation ADC Licensed Product may be subject to any recall, corrective action, patent regulatory procedures or other regulatory action in the Territory or the Retained Territory by any Governmental Authority or Regulatory Authority (a “**Remedial Action**”). The Parties shall assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. The Parties shall collaborate in good faith and endeavor to reach an agreement on Remedial Action related decisions save that where there is any unsettled issues in relation to any Remedial Action related matters (i) with respect to the Territory, Licensee shall have the final decision making authority and Duality shall take all actions reasonably requested by Licensee in relation to such Remedial Action, save that where such Remedial Action is reasonably likely to impact Duality’s position in respect of the Original ADC Licensed Product, the Next Generation ADC Licensed Product or any Regulatory Authorities in the Retained Territory, no action will be taken by Licensee (unless immediate action is required to comply with Applicable Laws and mitigate further damage arising from the Remedial Action) without Duality’s prior written consent, and (ii) with respect to the Retained Territory, Duality shall have the final decision making authority and Licensee shall take all actions reasonably requested by Duality in relation to such Remedial Action, save that where such Remedial Action is reasonably likely to impact Licensee’s position in respect of the Original ADC Licensed Product, the Next Generation ADC Licensed Product or any Regulatory Authorities in the Territory, no action will be taken by Duality without Licensee’s prior written consent. The cost and expenses of any Remedial Action shall be borne by the Party whose action or inaction caused the Remedial Action of the Original ADC Licensed Product or the Next Generation ADC Licensed Product.

Article 6 MANUFACTURE & SUPPLY

6.1 Costs of CMC Activities. Duality will conduct CMC activities for the Original ADC Licensed Products and/or, after Next Generation Option Exercise, the Next Generation ADC Licensed Product according to the scope as agreed upon by the Parties in the Development Plan. [***]

6.2 Transfer of CMC Materials from Duality to Licensee, and transfer of Manufacturing process. In addition to the CMC documentation in the Know-How transfer under Section 2.6 above, within [***] following Licensee’s request (such request is at any time during the Term at Licensee’s discretion), and thereafter from time to time during the Term upon Licensee’s reasonable advance request and to the extent not previously provided, Duality shall provide to Licensee (or its designees) the updated CMC-related technical documents and CMC-related technology (and any associated manufacturing process technology with regards to manufacturing of antibody, the linker-payload and the DS, DP (drug substance, drug product) of the Licensed Compound), in original form and English language certified translations, that are necessary or reasonably useful for the Manufacture of the Licensed Compound and Original ADC Licensed Product, and/or, after Next Generation Option Exercise, for the Manufacture of the Next Generation Licensed Compound and the Next Generation ADC Licensed Product and are Controlled by Duality or any of its Affiliates as of the Effective Date and which become Controlled by Duality or any of its Affiliates during the Term (“**CMC Materials**”), and all customs and technology export licenses required by Applicable Law for such transfer(s), if any. Within [***] of Licensee’s request, Duality or a Duality CMO shall provide Licensee (or its designee) with reasonable consultation and on-site support in respect of the CMC-related technology and associated manufacturing process technology transferred to Licensee pursuant to this Section 6.2. Any assistance required from Duality or Duality’s CMO, the [***] will be free

of charge to Licensee. Any additional assistance in excess of [***] will be at the Licensee's cost and expense, provided that Licensee will in this case pay the reasonable and market standard FTE rate incurred by Duality's or Duality CMO's employees involved in such consultation and/or on-site support. For clarity, Licensee will not pay any manufacturing technology transfer fee owed by Duality to a Duality CMO or another Third Party. The conclusion of new Third Party agreements regarding the CMC activities contemplated under Section 6.1 or the amendment of existing Third Party agreements regarding the same shall be subject to Licensee's prior written approval.

6.3 Transfer of Cell Banks. The Parties will enter into a separate quality agreement and thereafter a supply agreement to manage the logistics and shipping of the transfer of the MCB and WCB (collectively, including cell banks that are developed in future, "Cell Banks") used for the Manufacturing of the Antibody incorporated into the Licensed Products, with the respective negotiations to be commenced within [***] days after the Effective Date. [***]

6.4 Initial Clinical Supply. Except for [***] and Licensee's agents, which supply shall be provided by Licensee in accordance with Section 4.2(c) and 4.2(d), Duality shall, by itself or through one or more Duality CMO(s) in the Retained Territory, supply to Licensee [***] to Licensee's designated location [***] and in accordance with a separate clinical supply agreement as contemplated below; provided that Licensee shall be [***]. Unless otherwise agreed by the Parties, the Parties shall negotiate in good faith a clinical supply agreement and related quality agreement with such negotiation to be commenced within [***] days after the Effective Date and, unless otherwise agreed between the Parties, completed no later than [***] days after the Effective Date, which clinical supply agreement shall contain customary language regarding supply of the Licensed Compound or Original ADC Licensed Products, or, after Next Generation Option Exercise, the Next Generation ADC Licensed Products to Licensee (including equitable allocation in the event of disruption to or shortage of product supply, and Licensee's right to audit any of Duality's or its Affiliates', or any of their respective CROs' or CMOs' manufacturing sites). [***]

6.5 Ongoing Supply. Except as may otherwise be provided under the clinical supply agreement entered into by the Parties pursuant to Section 6.4 and until the Licensee has qualified a new manufacturing site to Manufacture the Licensed Compound and the Original ADC Licensed Products, or after Next Generation Option Exercise the Next Generation Licensed Compound and the Next Generation ADC Licensed Product in the Territory, Duality shall be solely responsible for Manufacturing the Licensed Compound and Original ADC Licensed Products and/or after Next Generation Option Exercise, the Next Generation Licensed Compound and the Next Generation ADC Licensed Product intended for use (either Clinical Trial use or commercial use) in the Territory, and Licensee shall be solely responsible for the associated costs and expenses of such Manufacturing activities. Once the Original ADC Licensed Product or Next Generation ADC Licensed Product is approved, [***].

Article 7 COMMERCIALIZATION MATTERS

7.1 Overview; Diligence. Subject to the terms and conditions of this Agreement (including the diligence obligations set forth below), Licensee (itself or through its Affiliates or Sublicensees, as applicable) shall be solely responsible for Commercialization of the Original ADC Licensed Products or after Next Generation Option Exercise, the Next Generation ADC Licensed Product in the Field in the Territory, including: (i) developing and executing a commercial launch and pre-launch plan, (ii) developing the global pricing strategy and negotiating with applicable Governmental Authorities regarding price and reimbursement of such Original

ADC Licensed Products or Next Generation ADC Licensed Products; (iii) marketing, advertising and promotion; (iv) booking sales; (v) distribution and handling all aspects of order processing, invoicing and collection, inventory and receivables; (vi) providing customer support, and performing other related functions; (vii) conforming its practices and procedures to Applicable Laws relating to the marketing, detailing and promotion of the Original ADC Licensed Products or Next Generation ADC Licensed Products in the Field; and (viii) developing and implementing the global and local Medical Affairs Activities and medical information infrastructure required in the Field in the Territory. Licensee shall bear all of the costs and expenses incurred in connection with such Commercialization activities in the Territory. Licensee shall use Commercially Reasonable Efforts to launch [***] in [***]. For the avoidance of doubt, Licensee shall have fulfilled its diligence obligation under this Section 7.1 if it has used Commercially Reasonable Efforts to launch either the Original ADC Licensed Products or the Next Generation ADC Licensed Product in [***].

7.2 Commercialization Plan. No later than [***] months before the anticipated date of the submission of the first MAA for an Original ADC Licensed Product or, after Next Generation Option Exercise, the Next Generation ADC Licensed Product in the Territory, Licensee shall prepare a written Commercialization plan that sets forth the timeline and details of all major Commercialization activities planned for such Original ADC Licensed Product or such Next Generation ADC Licensed Product in the Territory (the “**Commercialization Plan**”). The Commercialization Plan shall be updated [***].

7.3 Coordination of Commercialization Activities. The Parties recognize that they may benefit from the coordination of certain activities in support of the Commercialization of an Original ADC Licensed Product or Next Generation ADC Licensed Product across their territories. As such, the Parties may coordinate such activities where appropriate, including scientific and medical communication and Original ADC Licensed Product or Next Generation ADC Licensed Product positioning. For clarity, Licensee shall not conduct any Commercialization of any Original ADC Licensed Product or Next Generation ADC Licensed Product outside the Territory without Duality’s express prior written consent and Duality shall not conduct any Commercialization of Original ADC Licensed Products or Next Generation ADC Licensed Product outside of the Retained Territory without Licensee’s express prior written consent.

7.4 Commercialization Reports.

(a) Licensee shall keep Duality informed of its, its Affiliates’ and Sublicensees’ Commercialization activities in the Territory with respect to each Original ADC Licensed Product or Next Generation ADC Licensed Product and Duality shall keep Licensee informed of Duality’s, its Affiliates’ and sublicensees’ Commercialization activities in the Retained Territory with respect to each Original ADC Licensed Product or Next Generation ADC Licensed Product. All information and reports provided to the other Party in such report shall be treated as Confidential Information of the disclosing Party.

(b) Licensee shall, [***], provide Duality with [***].

(c) In addition to the other provisions of this Section, each Party shall make available to the other Party such additional information about its Commercialization activities with respect to an Original ADC Licensed Product or after Next Generation Option Exercise, Next Generation ADC Licensed Product as may be reasonably requested by the other Party from time to time.

7.5 Trademarks. Licensee shall be responsible for the registration, filing, maintenance and enforcement of any trademarks (including domain names) developed for the Original ADC Licensed Products or, after Next Generation Option Exercise, the Next Generation

ADC Licensed Product, in the Field in the Territory (the “**Product Marks**”). The Parties will discuss in good faith and enter into a separate branding agreement outlining terms for ownership, use, management and enforcement of trademarks (including domain names) adopted to identify the Original ADC Licensed Products or Next Generation ADC Licensed Products in the Field in the Retained Territory.

7.6 Original ADC Licensed Products Tracking in the Territory and Retained Territory . Licensee shall, and shall ensure that its Affiliates and Sublicensees, maintain adequate records to permit the Parties to trace the distribution, sale, and use of all Original ADC Licensed Products or, after Next Generation Option Exercise, the Next Generation ADC Licensed Product, through all relevant channels (e.g. wholesalers, hospitals and pharmacies) in the Territory. Duality shall, and shall ensure that its Affiliates and sublicensees, maintain adequate records to permit the Parties to trace the distribution, sale, and use of all Original ADC Licensed Products or, after Next Generation Option Exercise, all Next Generation ADC Licensed Product, through all relevant channels (e.g. wholesalers, hospitals and pharmacies) in the Retained Territory.

7.7 No Diversion. Each Party hereby covenants and agrees that during the Term, and except as expressly permitted by this Agreement, it shall not (and shall cause its Affiliates and Sublicensees (with respect to Licensee), sublicensees (with respect to Duality) and subcontractors not to), either itself or through a Third Party, develop, use, market, promote, import, export, sell or actively offer for sale (online or otherwise) the Original ADC Licensed Products or, after Next Generation Option Exercise, the Next Generation ADC Licensed Products, in the other Party’s territory. Without limiting the generality of the foregoing, except as mutually agreed by the Parties, each Party shall not (a) engage in any advertising activities relating to the Original ADC Licensed Products or Next Generation ADC Licensed Products, directed primarily to customers in the other Party’s territory, or (b) actively or intentionally solicit orders from any prospective purchaser located in the other Party’s territory or prospective purchasers whose delivery address is located in the other Party’s territory. To the extent permitted by Applicable Laws, including applicable antitrust laws, if a Party receives any order for Original ADC Licensed Products or Next Generation ADC Licensed Products from a prospective purchaser located in or with a nominated delivery address in a country or jurisdiction in the other Party’s territory, such Party shall immediately refer that order to the other Party and shall not accept any such order or deliver or tender (or cause to be delivered or tendered) the for Original ADC Licensed Products or Next Generation ADC Licensed Products under such order. If a Party should reasonably know that a customer or distributor is actively engaged itself or through a Third Party in the sale or distribution of the for Original ADC Licensed Products or Next Generation ADC Licensed Products in the other Party’s territory, then such Party shall (i) within [***] Days of gaining knowledge of such activities, notify the other Party regarding such activities and provide all information available to such Party that the other Party may reasonably request concerning such activities and (ii) use Commercially Reasonable Efforts (including cessation of sales or delivery to such customer) necessary to limit such sale or distribution in the other Party’s territory, unless otherwise agreed in writing by the Parties prior to such sale or delivery.

Article 8 FINANCIAL TERMS

8.1 Upfront Payment. In partial consideration of Duality’s granting of the licenses and rights to Licensee hereunder, Licensee shall make a one-time, non-refundable, non-creditable payment to Duality of [***] (the “**Upfront Payment**”) within [***] days after receipt of an invoice issued by Duality to the Licensee on or after the Effective Date.

8.2 [***].

(a) [***].

(b) **Invoicing.** No later than [***] setting forth the amount of actual Duality Costs for the Planned Trials and Original ADC Added Trials (if any) incurred during such Calendar Quarter in the Territory which shall be reimbursed by Licensee pursuant to this Section 8.2, along with supporting documentation itemizing the breakdown of the costs and expenses that were incurred and are reimbursable hereunder. Each invoice issued by Duality shall list Duality Costs [***] in the Territory actually incurred in U.S. Dollars (and if any item was originally in another currency, the exchange rate used for converting the original currency to U.S. Dollar in accordance with Section 9.3). [***]

(c) **Other Clinical Trials.** At Licensee's request, Duality shall perform any other Clinical Trial of an Original ADC Licensed Product (other than the Planned Trials or Original ADC Added Trials) or of an Next Generation ADC Licensed Product (other than the Next Generation Added Trials). The Parties shall discuss (through the JSC) Licensee's funding [***].

8.3 Development and Regulatory Milestone Payments of the Original ADC Licensed Product or Next Generation ADC Licensed Product. With respect to the milestone events set forth in the tables below, promptly following the first achievement, whether by Duality or any of Duality's Affiliates (when designated by Licensee) or by Licensee or any of Licensee's Affiliates or Sublicensees, of the corresponding milestone event by the first Original ADC Licensed Product, or after the Next Generation Option Exercise, the Next Generation ADC Licensed Product, whichever first reaches the respective milestone event for the first time, up to [***] Indications only. Licensee or Duality, as the case may be, shall notify the other Party within [***] Days of such achievement, and Licensee shall pay to Duality the corresponding non-refundable, non-creditable milestone payment within [***] days after the receipt of an invoice issued by Duality to Licensee on or after the achievement of the applicable milestone event:

[***]

[***]

[***]

[***]

8.4 Sales Milestone Payments of the Original ADC Licensed Products. Licensee shall pay to Duality the additional one-time, non-refundable, non-creditable payments set forth in the table below within [***] days after receipt of an invoice issued by Duality to Licensee on or after the first achievement of each milestone event described below. [***]

[***]

Within [***] days after the end of the Calendar Quarter in which any milestone event set forth above in this Section 8.4 for which a milestone payment is payable is achieved, Licensee shall deliver a written notice to Duality of such achievement, and Licensee shall pay to Duality the corresponding milestone payment within [***] days after the receipt of an invoice issued by Duality to Licensee. For clarity, each of the milestone payments set forth above in this Section 8.4 shall be additive such that if multiple milestone events specified above are achieved

in the same Calendar Quarter, then the milestone payments for all such milestone events shall be payable by Licensee.

8.5 Sales Milestone Payments of the Next Generation ADC Licensed Product. After Next Generation Option Exercise and the First Commercial Sale of the Next Generation ADC Licensed Product, Licensee shall pay to Duality the additional one-time, non-refundable, non-creditable payments set forth in the table below within [***] days after receipt of an invoice issued by Duality to Licensee on or after the first achievement of each sales milestone event described below. [***].

[***]

Within [***] days after the end of the Calendar Quarter in which any milestone event set forth above in this Section 8.5 for which a milestone payment is payable is achieved, Licensee shall deliver a written notice to Duality of such achievement, and Licensee shall pay to Duality the corresponding milestone payment within [***] days after the receipt of an invoice issued by Duality to Licensee. For clarity, each of the milestone payments set forth above in this Section 8.5 shall be additive such that if multiple milestone events specified above are achieved in the same Calendar Quarter, then the milestone payments for all such milestone events shall be payable by Licensee.

8.6 Royalties. Licensee shall pay tiered royalties to Duality on Annual Net Sales of:

(i) all Original ADC Licensed Products in the Territory [***] in each Calendar Quarter as set forth below in table 1 in this Section 8.6, calculated by [***];

(ii) all Next Generation ADC Licensed Products in the Territory [***] in each Calendar Quarter as set forth below in table 2 in this Section 8.6, calculated by [***];

(iii) any [***] and/or [***] at the Reduced Royalty Rates for each respective Annual Net Sales threshold as set forth in tables 3 and 4 in this Section 8.6 respectively, calculated by [***];

Table 1

[***]

Table 2

[***]

Table 3

[***]

Table 4

[***]

8.7 Royalty Term. Royalties under Section 8.6 shall be payable, on [***] basis, during the period beginning on the date of [***] and continuing until the latest of: [***] (the “**Royalty Term**”).

8.8 Royalty Payment Reduction of Licensed Products

[***]

Article 9 PAYMENT; RECORDS; AUDITS

9.1 Payment; Reports. Royalties shall be calculated and reported for each Calendar Quarter within [***] days after the end of each Calendar Quarter. Each payment shall be accompanied by a report of [***]. Except as may otherwise be expressly provided herein, Licensee shall not have the right to set off, withhold or make any deduction from any payment of royalties or other payments due to Duality hereunder for any reason whatsoever.

9.2 Invoices. Duality will ensure that all invoices:

- (a) are delivered in accordance with the procedures set out in **Schedule 9.2**;
- (b) are in such form as Licensee reasonably requires; and
- (c) incorporate all information required by Licensee, as set out in **Schedule 9.2**.

9.3 Exchange Rate; Manner and Place of Payment. All payments hereunder shall be payable in U.S. dollars within [***] days after receipt of an invoice from Duality. With respect to sales of Licensed Products invoiced in a currency other than U.S. dollars, sales milestones and royalties shall be converted into U.S. dollar using the exchange rate mechanism generally applied by Licensee or its Affiliates or Sublicensees for consolidation purposes, in accordance with the Accounting Standards, for the Calendar Quarter for which a payment is due. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Duality, unless otherwise specified in writing by Duality.

9.4 Taxes.

(a) **Taxes on Income.** Except as otherwise provided in this Section 9.4, Licensee shall be solely responsible for the payment of all value added taxes, fees, duties, surcharges, and other deductions or withholding taxes imposed by or on any entity in the Territory in connection with the payments and activities contemplated hereunder. Except as otherwise set forth in this Section, each Party shall be solely responsible for the payment of all taxes imposed on such Party's income arising directly or indirectly from the activities of the Parties under this Agreement.

(b) **Tax Withholdings.** In the event that any withholding tax, fee, duty or surcharge applicable to or assessable in respect of any of the Upfront Payment, development, regulatory or sales milestone payments, or royalty payments to be made by Licensee to Duality under this Agreement (collectively, the "**License Payments**") is required to be withheld and deducted under Applicable Laws ("**Tax Withholdings**"), Licensee (or its Affiliate paying on behalf of Licensee) shall make such deduction and withholding and will pay the remaining License Payments to Duality. For clarity, Licensee's reimbursement of Duality Costs in the Territory shall not be deemed to be License Payments or subject to any Tax Withholdings. If Licensee did not conduct the Tax Withholding when making its payment(s) to Duality, but is later determined by Applicable Law to pay an amount of tax on account of Duality to the tax authorities, Duality will promptly refund that amount of Tax Withholdings to Licensee, provided that Duality shall not be liable for any interest or other penalty on such payments.

(c) **Tax Cooperation.** Licensee shall make such deduction of taxes and withholding tax payments to the applicable taxing authority(ies) in a timely manner and shall promptly provide Duality with the appropriate proof of payment and relevant receipt(s) with respect to such deduction or withholding. To the extent permitted by Applicable Laws, Licensee shall provide Duality reasonable assistance in order to allow Duality to obtain the benefit of any present or future treaty against double taxation or refund or reduction in taxes which may apply to the License Payments. Each Party agrees to use commercially reasonable efforts to cooperate with the other Party in claiming refunds, reductions, or exemptions from such deductions or withholdings under any relevant agreement or treaty that is in effect. Duality will provide Licensee with any tax forms or other documentation reasonably necessary in order for Licensee not to withhold or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. If the taxes originally paid or otherwise borne by a Party are in whole or in part subsequently determined not to have been chargeable, all reasonably necessary steps will be taken by each Party to obtain a refund of these undue taxes from the applicable Governmental Authority or other fiscal authority and any amount of undue taxes repaid by such authority to the receiving Party will be transferred to the paying Party within [***] days of receipt.

9.5 Blocked Currency. In the event that, by reason of Applicable Law in any country or region, it becomes impossible or illegal, after reasonable efforts by Licensee to do so, for Licensee or its Affiliate to transfer, or have transferred on its behalf, payments owed Duality hereunder, Licensee shall promptly notify Duality of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country or region to the credit of Duality in a recognized banking institution designated by Duality provided such arrangements are legal under all Applicable Laws.

9.6 Records; Audits. Licensee shall keep, and require its Affiliates and Sublicensees to keep, complete, fair and true books of accounts and records for the purpose of determining the amounts payable to Duality pursuant to this Agreement. Such books and records shall be kept for at least [***] Years following the end of the Calendar Year to which they pertain. Duality shall have the right to cause an independent, certified public accountant reasonably acceptable to Licensee to audit such records to confirm Net Sales, royalties and other payments for a period covering not more than the preceding [***] Years; provided that (a) such audit shall not be more frequent than once in any [***] month period, and (b) once such accountant has conducted a review and audit of any records pursuant to this Section 9.6 in respect of any given period, it may not subsequently re-inspect such records with respect to such period, unless, in each case of (a) and (b), for cause. Prior to engagement by an independent, certified public accountant, such accountant must have executed and delivered to Licensee and its Affiliates a confidentiality agreement as reasonably requested by Licensee, which will include provisions limiting such accountant's disclosure to Duality to only the results and basis for such results of such inspection. Such audits may be exercised during normal business hours upon reasonable prior written notice to Licensee. Prompt adjustments shall be made by the Parties to reflect the results of such audit. Duality shall bear the full cost of such audit unless such audit discloses an underpayment by Licensee of more than [***] of the amount of royalties or other payments due under this Agreement for any applicable Calendar Quarter, in which case, Licensee shall bear the cost of such audit and shall promptly remit to Duality the amount of any underpayment. Any overpayment by Licensee revealed by an audit shall be fully-creditable against future payment owed by Licensee to Duality (and if no further payments are due, shall be refunded by Duality at the request of Licensee). Any underpayment by Licensee identified by an audit shall not be subject to Section 9.7.

9.7 Late Payments. In the event that either Party fails to make any payment due under this Agreement (save as set out in Section 9.6), simple interest shall thereafter accrue on the sum due from the due date until the date of payment at [***].

Article 10
CONFIDENTIALITY

10.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party (in such capacity, the “**Receiving Party**”) agrees that, during the Term and for [***] years thereafter, it shall keep confidential and shall not publish or otherwise disclose to any Third Party, and shall not use for any purpose other than as expressly provided for in this Agreement or any other written agreement between the Parties, any Confidential Information, including any Know-How, furnished or made available to it by or on behalf of the other Party (in such capacity, the “**Disclosing Party**”). The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to ensure that its, and its Affiliates’, employees, agents, contractors, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information. The Receiving Party shall promptly notify the Disclosing Party upon discovery of any unauthorized use or disclosure of the Disclosing Party’s Confidential Information.

10.2 Exceptions. Confidential Information shall not include any information which the Receiving Party can prove by competent evidence: (a) is at the time of disclosure, or thereafter becomes, through no act or failure to act on the part of the Receiving Party, generally known or available to the public or part of the public domain; (b) is known by the Receiving Party and/or any of its Affiliates at the time of receiving such information, as evidenced by its records; (c) is hereafter furnished to the Receiving Party and/or any of its Affiliates by a Third Party, as a matter of right and without restriction on disclosure; or (d) is independently discovered or developed by the Receiving Party and/or any of its Affiliates, without the use of or reference to Confidential Information of the Disclosing Party.

10.3 Authorized Disclosure. Notwithstanding the provisions of Section 10.1, the Receiving Party may disclose Confidential Information of the Disclosing Party as expressly permitted by this Agreement, or if and to the extent such disclosure is reasonably necessary in the following instances:

- (a) filing or prosecuting or defending Patents as permitted by this Agreement;
- (b) disclosure required in connection with any judicial, regulatory or administrative process relating to or arising from this Agreement (including any enforcement hereof) or to comply with applicable court orders;
- (c) disclosure to Affiliates, employees, contractors, consultants or agents of the Receiving Party who have a need to know such information in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement; provided, in each case, that any such Affiliate, actual or potential licensee or Sublicensee, employee, contractor, consultant or agent agrees to be bound by terms of confidentiality and non-use comparable in scope to those set forth in this Article 10;
- (d) such disclosure is made to such Party’s attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the Receiving Party, on the condition that such attorneys, independent accountants and financial advisors are bound by confidentiality and non-use obligations consistent with the confidentiality provisions of this Agreement as they apply to the Receiving Party (provided, however, that in the case of financial advisers, including investment bankers, the term of confidentiality may be

shortened to [***] years from the date of disclosure and in the case of attorneys, no written agreement shall be required);

(e) disclosure to existing investors, acquirors or collaborators or potential bona fide investors, acquirors, licensees, Sublicensees or collaborators in connection with due diligence or similar investigations by such Third Parties; provided, in each case, that any such existing or potential investor, acquiror, licensee, Sublicensee or collaborator agrees to be bound by confidentiality and non-use obligations consistent with those contained in this Agreement as they apply to the Receiving Party (but of duration customary in confidentiality agreements entered into for similar purpose);

(f) disclosure to Regulatory Authorities as required by Applicable Laws in relation to Regulatory Approvals and regulatory procedures, proceedings and other filings;

(g) disclosure to: (i) Governmental Authorities to the extent useful or necessary to make regulatory filings and obtain or maintain Regulatory Approvals (including fulfilling post-approval regulatory obligations) for any Licensed Product; (ii) Governmental Authorities, technical committees or similar public health or scientific bodies for purposes of securing product use recommendations, tenders, direct procurement contracts or responding to relevant requests for information; (iii) comply with Applicable Laws with respect to performance under this Agreement; and (iv) to Governmental Authorities in order to respond to inquiries, requests or investigations relating to Licensed Products or this Agreement; and

(h) to the extent mutually agreed to by the Parties in writing.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 10.3(a) or Section 10.3(b), it will, except where impracticable for necessary disclosures, give reasonable advance notice to the other Party of such disclosure requirement and will use its reasonable efforts to secure and cooperate with the other Party, as necessary, to seek and obtain confidential treatment of such Confidential Information required to be disclosed to the extent legally permissible and will limit the disclosure of that Confidential Information required to be disclosed to (i) to advisors (including lawyers and accountants) or Governmental Authorities on a need to know basis, in each case under appropriate confidentiality provisions or professional standards of confidentiality substantially equivalent to those of this Agreement, or (ii) to the extent agreed to by the Parties.

10.4 Public Announcements.

(a) Press Releases and Publicity.

(i) As soon as practicable following the Effective Date and on a date mutually agreed by the Parties, Duality shall issue a press release announcing the execution of this Agreement in substantially the form attached hereto as **Schedule 10.4**. Except as required by applicable securities laws (including disclosure requirements of the U.S. Securities and Exchange Commission ("SEC") or any stock exchange on which securities issued by a Party or its Affiliates are traded), neither Party shall make any other public announcement or statement, whether oral or written, concerning this Agreement or the subject matter hereof without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed; provided that each Party may make any public statement in response to questions by the press, analysts, investors or those attending industry conferences or financial analyst calls, or issue press releases, so long as any such public statement or press release is not inconsistent with prior public disclosures or public statements approved by the other Party pursuant to this Section 10.4

and which do not reveal non-public information about the other Party. In the event of a required public announcement, to the extent practicable under the circumstances, the Party making such announcement shall provide the other Party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other Party a reasonable opportunity to review and comment upon the proposed text. Licensee shall have final decision making authority in respect of the proposed text of any required public announcement relating to the Licensed Product in the Territory and Retained Territory.

(ii) In the event of termination of this Agreement for any reason, if in the reasonable opinion of the either Party's legal counsel, public disclosure of such termination is required under the Applicable Law or the rules of a stock exchange on which the securities of either Party (or any controlling Affiliate of such Party) are listed (or to which an application for listing has been submitted), the Parties shall cooperate in good faith to coordinate public disclosure, if any, of such termination and the reasons therefor. The principles to be observed in such disclosures shall be accuracy, compliance with Applicable Law, the rules of the applicable stock exchange and regulatory guidance documents, and reasonable sensitivity to potential negative investor reaction to such news and neither Party shall make any other public announcement or statement, whether oral or written, concerning the termination of this Agreement without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed.

(iii) Notwithstanding anything to the contrary in this Section 10.4, and subject to Section 10.5, the Parties have the right to publicly disclose (A) the achievement of milestones under this Agreement; and (B) the commencement, completion, material data and key results of Clinical Trials conducted under this Agreement. After a publication has been made available to the public, each Party may post such publication or a link to it on its corporate web site without the prior written consent of the other Party.

(b) **Filing of this Agreement.** The Parties shall coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the SEC or any stock exchange or governmental agency on which securities issued by a Party or its Affiliate are traded, and each Party will use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; provided that each Party will ultimately retain control over what information to disclose to the SEC or any stock exchange or other governmental agency, as the case may be, and provided further that the Parties will use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither Party (nor its Affiliates) will be obligated to consult with or obtain approval from the other Party with respect to any filings to the SEC or any stock exchange or other governmental agency.

10.5 Publication.

(a) If either Party proposes to publicly present or publish, in any publication or venue, in their respective Territories, any Clinical Trial data, non-clinical data or any associated results or conclusions generated by or on behalf of Licensee pursuant to Clinical Trials (each such proposed presentation or publication, a "**Proposed Publication**"), it shall obtain the other Party's prior written consent and otherwise comply with this Section 10.5. The proposing Party shall provide the other Party with a copy of such Proposed Publication at least [***] days prior to the earlier of its presentation or intended submission for publication; provided that in the case of abstracts, this period shall be at least [***] Days (such applicable period, the "**Review Period**"). The proposing Party agrees that it will not submit or present any Proposed Publication (i) until the other Party has provided written

comments during such Review Period on the material in such Proposed Publication or (ii) until the applicable Review Period (as may be extended by subsection (C) below) has elapsed without written comments from the other Party, in which case the proposing Party may proceed and the Proposed Publication will be considered approved in its entirety. If the proposing Party receives written comments from the other Party during the applicable Review Period, it shall consider the comments of the other Party in good faith, but will retain the sole authority to submit the manuscript for such Proposed Publication; provided that the proposing Party agrees to (A) delete any Confidential Information of the other Party that the other Party identifies for deletion in the other Party's written comments, (B) delete any Clinical Trial data, non-clinical data, results, conclusions or other related information that is not specific to or resulting from any Clinical Trial conducted in the proposing Party's territory, and (C) delay such Proposed Publication for a period of up to an additional [***] days after the end of the applicable Review Period to enable the other Party to draft and file patents with respect to any subject matter to be made public in such Proposed Publication and to which the other Party has the applicable intellectual property rights to file such patents. The proposing Party shall provide the other Party a copy of the Proposed Publication at the time of the submission or presentation. The proposing Party shall require its Affiliates, (sub)licensees (in case that Duality is the proposing Party), Sublicensees (in case that Licensee is the proposing Party) and contractors to comply with the obligations of this Section 10.5 as if they were the proposing Party, and shall be liable for their non-compliance.

10.6 Publication and Listing of Clinical Trials. Each Party agrees to comply, with respect to the listing of Clinical Trials or the publication of Clinical Trial information and results with respect to Licensed Products and to the extent applicable to its activities conducted under this Agreement, with any Applicable Law or applicable court order, stipulations, consent agreements and settlements entered into by such Party; provided that any listings or publications made pursuant to this Section 10.6 shall be considered a publication hereunder and shall be subject to Section 10.5.

10.7 Prior Non-Disclosure Agreement. As of the Effective Date, the terms of this Article 10 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) to the extent dealing with the subject of this Agreement. Any information disclosed pursuant to any such prior agreement relating to the subject to this Agreement shall be deemed Confidential Information for purposes of this Agreement.

10.8 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that would result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages would not be a sufficient remedy for any breach of this Article 10. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 10.

Article 11 REPRESENTATIONS AND WARRANTIES; LIMITATION OF LIABILITY

11.1 Mutual Representations and Warranties. Each Party represents and warrants to the other that, as of the Effective Date:

(a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action;

(c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not (i) conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, (ii) conflict with or result in a breach of any provision of its organizational documents, or (iii) violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and

(d) each Party shall conduct, and shall cause its Affiliates and Sublicensees (in the case of Licensee) and sublicensees (in the case of Duality) to conduct all activities under this Agreement in compliance with all Applicable Laws, all applicable national and international guidelines and any Regulatory Authority and Governmental Authority health care programs having jurisdiction, each as may be amended from time to time.

11.2 Additional Duality Representations and Warranties.

11.2.1 Duality represents and warrants to Licensee, as of the Effective Date and/or such any other date(s) expressly stated, subject to a Disclosure Schedule (attached here to as Schedule 11.2) (the “**Disclosure Schedule**”), as may be updated as further described in Section 11.8 below as follows:

[***]

11.2.2 [***]

11.2.3 [***]

11.3 Additional Licensee Representations and Warranties. Licensee represents and warrants to Duality, as of the Effective Date:

[***]

11.4 Mutual Covenants. In addition to any covenants made by the Parties elsewhere in this Agreement, each Party hereby covenants to the other that:

(a) (i) all patient authorizations and consents required under Applicable Laws (in connection with any applicable clinical study) permit the granting of access of Data that such Party is required to provide to the other Party pursuant to Section 5.6, and (ii) it will comply with Applicable Laws in transferring personal and other Data in connection with the granting of access of Data that such Party is required to provide to the other Party pursuant to Section 5.6. Each Party will obtain all the necessary authorizations, consents and approvals in order for such Party to grant access to its Data with the other Party, including obtaining the necessary patient authorizations and consents, and obtaining the necessary approvals from and completing all necessary filing procedures with the applicable Governmental Authorities in the Territory and within the Retained Territory (to the extent required to preserve Licensee’s position in the Territory);

(b) it will not knowingly, during the Term, employ or use the services of any person who is debarred or disqualified in connection with activities relating to the Licensed Compound or Licensed Products; and in the event that it becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing

services to it with respect to any activities relating to the Licensed Compound or Licensed Products, it will immediately notify the other Party in writing and it will cease employing, contracting with, or retaining any such person to perform any services relating to the Licensed Compound or Licensed Products;

(c) it shall conduct, and shall cause its Affiliates, subcontractors, Sublicensees (in the case of Licensee) or sublicensees (in the case of Duality) to conduct all activities under this Agreement (including, as set forth in the Development Plan(s) and Commercialization Plan(s) (as may apply) with respect to the Licensed Products in the Field in the Territory) in compliance with all Applicable Laws, and any Regulatory Authority and Governmental Authority health care programs having jurisdiction, each as may be amended from time to time;

(d) it shall conduct its obligations with respect to Development of the Licensed Products in the Territory in adherence with the Development Plan (including the Development Budget) as may be amended from time to time;

(e) it shall comply, and ensure that shall use commercially reasonable efforts to cause its Affiliates, subcontractors and Sublicensees (in case of Licensee) or sublicensees (in case of Duality) to comply with and commit to uphold the ABC Terms in the performance of activities under this Agreement;

(f) it shall have (and shall ensure its Affiliates, Sublicensees (in the case of Licensee) or sublicensees (in the case of Duality) and subcontractors as applicable, have), at all times, a reasonably sufficient number of suitably qualified personnel to allow the Party (or its Affiliates or Sublicensees (in the case of Licensee) or sublicensees (in the case of Duality) or subcontractors, as applicable) to conduct, in compliance with all Development timeframes set out in the applicable Development Plans and GXPs, any Clinical Trials that the Party is required to conduct with respect to the Licensed Products in its territory, or in the other Party's territory as permitted under this Agreement; and

(g) it shall not induce or solicit, or attempt to induce or solicit, any employees of the other Party or any of its Affiliates to leave the employment of, or to terminate his/her employment, services or engagement with, the other Party or its applicable Affiliate, or enter into any employment or services agreement or arrangement with such Party or any of its Affiliates.

11.5 Duality Covenants. In addition to any covenants made by Duality elsewhere in this Agreement, Duality hereby covenants to Licensee as follows:

[***]

11.6 Performance by Affiliates, Sublicensees and Subcontractors. (a) Subject to Licensee's prior written consent or if explicitly stated in the respective Development Plan or this Agreement, Duality may perform some or all of its respective obligations under this Agreement through one or more Affiliates, subcontractors or sublicensees, and (b) Licensee may perform some or all of its respective obligations under this Agreement through one or more Affiliates, subcontractors or Sublicensees; provided that with respect to the foregoing clauses (a) and (b), the Party involving its Affiliates, subcontractors or Sublicensees (in case of Licensee) or sublicensees (in case of Duality) shall at all times be fully responsible for the performance and payment of such Affiliate, subcontractor or Sublicensees (in case of Licensee) or sublicensees (in case of Duality).

11.7 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY DUALITY TO LICENSEE HEREUNDER ARE PROVIDED “AS IS,” AND DUALITY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OBTAINING SUCCESSFUL RESULTS, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

11.8 Updated Disclosure Schedule

(a) With respect to the Next Generation Licensed Compound, Next Generation ADC Licensed Product and the Duality Immune Agonist ADC Product that are subject to an option right, and subject to the occurrence of any change or event having a material adverse effect on it or which it believes would or would be reasonably likely to cause or constitute a material breach of any of its representations, warranties or covenants set forth herein, Duality shall be entitled to update the Disclosure Schedule (“**Updated Disclosure Schedule**”) in accordance with this Section 11.8.

(b) The right to update the Disclosure Schedule shall be limited to the respective option exercise period as set forth in Section 2.8 and 2.9 respectively and ends [***] Days before the option exercise period ends.

(c) Notwithstanding anything in this Agreement to the contrary, no update to the Disclosure Schedule pursuant to this Section 11.8 shall cure any breach of a representation or warranty of Duality contained in this Agreement with respect to the Original ADC Licensed Product and shall not affect any of the Licensee’s remedies with respect thereto.

**Article 12
INTELLECTUAL PROPERTY**

12.1 Ownership.

(a) **Background IP.** (i) Duality shall retain all right, title and interest in and to any Patents, Know-How, and other intellectual property rights Controlled by Duality or any of its Affiliates on or prior to the Effective Date or during the Term independent of the activities hereunder (the “**Duality Background IP**”), and (ii) Licensee shall retain all right, title and interest in and to any Patents, Know-How, and other intellectual property rights Controlled (other than pursuant to this Agreement) by Licensee or any of its Affiliates on or prior to the Effective Date or during the Term independent of the activities hereunder (the “**Licensee Background IP**”).

(b) **Solely Owned Collaboration IP and Solely Owned Collaboration Patents.**

[***]

(c) [***]

(d) [***]

(e) [***]

(f) [***]

(g) **Data and Regulatory Materials.** Notwithstanding anything contrary in this Section 12.1, the ownership rights to Regulatory Materials are allocated in accordance with Sections 5.2(b) and 5.4. The ownership rights to Data are allocated in accordance with Section 5.6.

(h) [***]

(i) **Disclosures; Cooperation.** Each Party shall, and shall ensure that each of its Affiliates, (sub)licensees (in the case of Duality), Sublicensees (in the case of Licensee) and subcontractors under this Agreement has a contractual obligation to disclose to such Party all Collaboration IP, Data and other Know-How generated, invented, discovered, developed, made or otherwise created by or for them or their employees, agents or independent contractors, and to provide sufficient documentary proof to evidence ownership, rights and interest with respect thereto, so that such Party can comply with its obligations under this Section 12.1.

(j) **Inventorship Determination.** [***]

12.2 Patent Prosecution and Maintenance.

(a) **Definition.** For purposes of this Section 12.2 and Sections 12.1(e), the terms “prosecute,” “prosecuting” and “prosecution,” when used in reference to any Patent, shall be deemed to include, without limitation, control of [***] with respect to such Patent.

(b) [***]

(c) [***]

(d) [***]

(e) [***]

12.3 Infringement by Third Parties.

(a) **Notice.** In the event that either Duality or Licensee becomes aware of any infringement or threatened infringement by a Third Party of any Solely Owned Collaboration Patent, Duality Product Patent, Duality Linker-Payload Patent, [***] and any related declaratory judgment or equivalent action, including administrative proceedings, alleging the invalidity, unenforceability or non-infringement of any such Patent, it shall notify the other Party in writing to that effect within [***] Days after becoming aware of such matter.

(b) [***]

(c) [***]

(d) [***]

(e) [***]

(f) [***]

12.4 Infringement of Third Party Rights.

[***]

12.5 Marking. [***]

12.6 Patent Listings. On a Licensed Product-by-Licensed Product basis, as between the Parties, [***] to make all patent listings of Duality Product Patents, Solely Owned Collaboration Patents, [***] or other patent-related submissions with Regulatory Authorities with respect to such Licensed Product, except for Duality Linker-Payload Patents [***], [***] to make all patent listings *provided that* [***] will be obliged to make all patent listings or other patent-related submissions with Regulatory Authorities in [***]. [***] reasonable requests in connection therewith, including meeting any submission deadlines, to the extent required or permitted by Applicable Laws.

12.7 Patent Right Term Extension. [***]

**Article 13
TERM; TERMINATION**

13.1 Term. The term of this Agreement (the “**Term**”) shall commence on the Effective Date, and unless terminated earlier as provided in this Article 13, shall continue in full force and effect, on a [***] except as provided otherwise in this Article 13.

13.2 [***]

13.3 Termination for Material Breach by Either Party.

(a) **Termination Right.** A Party shall have the right to terminate this Agreement (in its entirety or on a Licensed Product-by-Licensed Product and country-by-country basis) upon written notice to the other Party if such other Party is in material breach of this Agreement and has not cured such breach within [***] days after written notice from the terminating Party requesting cure of the breach. In case the alleged material breach is a material breach of Licensee’s diligence obligations set forth in Sections 4.1 and/or 7.1 of this Agreement, Duality shall only be entitled to terminate the Agreement with effect to the country or countries with respect to which Licensee has in fact materially breached the diligence obligations with respect to the Original ADC Licensed Product and not cured such breach. If at the end of the cure period the breaching Party has failed to perform the activities of the cure plan to cure the breach, the non-breaching Party shall be entitled to terminate the Agreement with [***] prior notice. If the existence of material breach or the failure to cure such material breach is not disputed by the breaching Party and the Agreement is terminated by the non-breaching Party, the consequences of termination set forth in Section 13.7 or Section 13.8 (as the case may be) shall apply. If the existence of material breach or the failure to cure such material breach is disputed by the breaching Party, Section 13.7 or Section 13.8 (as the case may be) shall apply if the existence of material breach or the failure to cure such material breach is determined pursuant to Section 15.2 and the Agreement is thereafter terminated by the breaching Party.

(b) **Dispute as to Material Breach.** In the event that the breaching Party disputes the existence of material breach or the failure to cure such material breach by

initiating arbitration proceedings pursuant to Section 15.2 within the cure period, the non-breaching Party shall not have the right to terminate in accordance with Section 13.3(a) unless and until the relevant dispute has been resolved pursuant to Section 15.2. During the pendency of such dispute, the applicable cure period shall be tolled, all the terms of this Agreement shall remain in effect, and the Parties shall continue to perform all of their respective obligations hereunder.

13.4 Termination for Other Causes.

(a) [***]

(b) **Bankruptcy.** A Party shall have the right to terminate this Agreement upon written notice to the other Party upon the filing or institution of bankruptcy, reorganization, dissolution, liquidation or winding up of such other Party, or the making or seeking to make or arrange an assignment of a substantial portion of such other Party's assets for the benefit of creditors of such other Party, or the initiation of proceedings in voluntary or involuntary bankruptcy against such other Party, or is adjudged bankrupt, or the appointment of a receiver or trustee of such other Party's property, in each case that is not discharged within [***] days, or immediately upon written notice to the Party, if such Party otherwise admits in writing to the other Party its inability generally to meet its obligations as and when they fall due in the general course of business. In the event a Party is bankrupted or a bankruptcy proceedings is commenced by or against such Party or its Affiliates or any country or jurisdiction, all rights under this Agreement will be fully exercisable and the bankrupt Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall continue to perform all of the obligations provided in this Agreement to be performed by such Party. If the bankrupt Party and its successors and assigns are restricted by Applicable Laws from performing its obligations hereunder and the other Party elects to retain its rights hereunder, then the bankrupt Party shall provide to the other Party copies of all information necessary for such other Party to prosecute, maintain and enjoy its rights under the terms of this Agreement promptly upon such other Party's written request therefor. All rights, powers and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity.

(c) [***]

(d) **Mutual Agreement.** The Parties may terminate this Agreement in full or on a Licensed Product-by-Licensed Product or a country-by-country basis, at any time during the Term upon mutual agreement in writing.

13.5 General Effects of Expiration or Termination.

(a) **Accrued Rights and Obligations.** Neither expiration nor any termination of this Agreement for whatsoever reason shall relieve either Party of any obligation or liability (including but not limited to any payment obligation under Article 8) accruing prior to such expiration or termination, nor shall expiration or any termination of this Agreement for whatsoever reason preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement. Such obligations and rights shall survive termination and expiration of this Agreement.

(b) **Termination of Non-Expired Options.** In case of termination of the entire Agreement, all non-expired option periods under the Agreement shall automatically

terminate. Upon termination of one or more Licensed Products, the option period shall only terminate with respect to the terminated Licensed Product(s).

(c) **Surviving Terms.** The Parties' rights and obligations under Article 1 (Definitions), Article 8 (Financial Terms, unless otherwise set out in this Article 13, the Financial Terms only survive with respect to Licensee's sell-off right in Sections 13.6(e), 13.7(b)(iv) and 13.8(b)(iii)); Article 9 (Payment); Article 10 (Confidentiality), Section 12.1 and with respect to [***] only Sections 12.2 and 12.4; Sections 13.5 to 13.10; Article 14 (Indemnification) other than Section 14.4 (Insurance); Article 15 (Dispute Resolution); Article 16 (Miscellaneous) of this Agreement shall survive expiration or any termination of this Agreement.

13.6 [*]**

- (a) **Licenses Granted to Licensee.** Upon termination of the entire Agreement, [***].
- (b) **Licenses Granted to Duality.** In case of termination of the entire Agreement, [***].
- (c) [***]
- (d) [***]
- (e) [***]
- (f) [***]
- (g) [***]
- (h) [***]

13.7 [*]**

- (a) [***]
- (b) [***]
- (i) [***]
- (ii) [***]

(iii) **Wind-Down or Transfer of Activities.** Licensee shall, as directed by Duality in its sole discretion, on a Clinical Trial-by-Clinical Trial basis, either:

[***]

- (iv) [***]

(v) **Sublicenses.** Duality shall grant to Licensee's or Licensee's Affiliate's Sublicensees a direct license; provided that (A) such sublicense agreement is consistent with the relevant terms and conditions of this Agreement at the time of termination of this Agreement, (B) such Sublicensee then is not in material breach of its sublicense agreement and (C) such Sublicensee then has not caused Licensee to be in material

breach of this Agreement due to any act or omission of such Sublicensee. The scope of such direct license shall be no less than the scope of the license granted in this Agreement and sublicensed to such Sublicensee and such direct license shall be on terms and conditions substantially similar to those set forth in this Agreement.

13.8 Consequences of Termination by Licensee for Material Breach or Patent Challenge by Duality. If an arbitration tribunal in accordance with the process set out in Section 15.2 confirmed (A) the existence of a material breach on the part of Duality, and such material breach was not or cannot be cured, or (B) in case of [***], with the Licensee’s Executive Officer having the final say, the following shall apply:

(a) [***]

(b) **Licensee’s Election to Terminate.** Licensee may terminate the Agreement in its entirety, on a country-by-country basis or on a Licensed Product-by-Licensed Product basis. In this case, the following would apply:

[***]

(c) [***]

13.9 [***]

13.10 [***]

Article 14 INDEMNIFICATION

14.1 Indemnification of Duality. Licensee shall indemnify and hold harmless each of Duality and its Affiliates and their respective directors, officers, employees, consultants, agents and successors and assigns of any of the foregoing (the “**Duality Indemnitees**”) from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys’ fees (“**Losses**”), incurred by any Duality Indemnitee as a result of any claims, demands, actions, suits or proceedings brought by a Third Party (“**Third Party Claims**”) arising directly or indirectly out of: (a) the practice by Licensee or its Affiliates or Sublicensees or subcontractors of the licenses granted to Licensee under this Agreement; (b) the research, Development, Manufacture or have Manufactured, use, handling, storage, Commercialization or other disposition of the Licensed Compound or the Licensed Products by Licensee or its Affiliates or Sublicensees or subcontractors; (c) the negligence or willful misconduct of any Licensee Indemnitee; or (d) any breach of any representations, warranties or covenants by Licensee under this Agreement; except, in each case, (x) to the extent such Third Party Claims fall within the scope of the indemnification obligations of Duality set forth in Section 14.2, or (y) arising from or occurring as a result of a Duality Indemnitee’s negligence, illegal conduct or willful misconduct in performing its or their obligations or exercising their rights under this Agreement. Licensee’s indemnification obligation specifically excludes any and all Third Party Claims for the use of any Patents, Know-How or other intellectual property rights under any Third Party agreements entered into by Duality prior to the Effective Date, including but not limited to the payment of royalties thereunder.

14.2 Indemnification of Licensee. Duality shall indemnify and hold harmless each of Licensee and its Affiliates and their respective directors, officers, employees, consultants, agents and successors and assigns of any of the foregoing (the “**Licensee Indemnitees**”), from and against any and all Losses incurred by any Licensee Indemnitee as a result of any Third Party Claims arising directly or indirectly out of: (a) the practice by Duality or its Affiliates or sublicensees or subcontractors of the license granted to Duality under Section 2.5; (b) the research,

Development, Manufacture or have Manufactured, use, handling, storage, Commercialization or other disposition of the Licensed Compound or Licensed Products by Duality or its Affiliates or sublicensees or subcontractors; (c) the negligence or willful misconduct of any Duality Indemnitee; or (d) any breach of any representations, warranties or covenants by Duality under this Agreement; except, in each case, (x) to the extent such Third Party Claims fall within the scope of the indemnification obligations of Licensee set forth in Section 14.1, or (y) arising from or occurring as a result of a Licensee Indemnitee's negligence, illegal conduct or willful misconduct in performing its or their obligations or exercising their rights under this Agreement. In addition to the above, and not subject to (x), regardless of any information provided by Duality to Licensee regarding Third Party Agreements entered into prior to the Effective Date, Duality's indemnification obligation shall cover any and all Third Party Claims for the use of any Patents, Know-How or other intellectual property rights under any Third Party Agreements entered into by Duality prior to the Effective Date, including but not limited to the payment of royalties thereunder.

14.3 Procedure. If any Duality Indemnitee or Licensee Indemnitee intends to claim indemnification under this Article 14 (the "**Indemnitee**"), Duality or Licensee, as the case may be, shall promptly notify the indemnifying Party (the "**Indemnitor**") in writing of any Third Party Claim, in respect of which the Indemnitee intends to claim such indemnification. Each indemnification claim notice must contain a description of the claim, the nature and amount of such loss (to the extent known at the time). The Indemnitor shall have sole control of the defense and/or settlement thereof and the Indemnitee shall be entitled to participate in (but not control) the defense of such Third Party Claim and to employ counsel of its choice for this purpose, at its own expense. The indemnity arrangement in this Article 14 shall not apply to amounts paid in settlement of any action with respect to a Third Party Claim, if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld, conditioned or delayed unreasonably. The failure to deliver written notice to the Indemnitee within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the Indemnitor of its indemnification obligations under this Article 14 if and to the extent the Indemnitee is actually prejudiced thereby. Duality or Licensee, as the case may be, and the Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Third Party Claim covered by these indemnification provisions. The Indemnitor shall not settle any Third Party Claim without the prior written consent of the Indemnitee if the settlement is reasonably expected to: (a) result in or impose any obligation (including any payment obligation) on the Indemnitee or otherwise adversely affect the business of the Indemnitee in any manner, or (b) result in any admission of wrong-doing or fault by the Indemnitee. The costs and expenses, including fees and disbursements of counsel, incurred by the Indemnitee in connection with any claim shall be reimbursed by the Indemnitor on a Calendar Quarter basis, without prejudice to the Indemnitor's right to contest the Indemnitee's right to indemnification and subject to refund in the event the Indemnitee is ultimately held not to be obligated to indemnify the Indemnitee.

14.4 Insurance. Each Party, at its own expense, shall maintain product liability and other appropriate insurance (or self-insure) in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement during the Term. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request. Such insurance shall not be construed to create a limit on either Party's liability with respect to its indemnification obligations under this Article 14.

14.5 [***]

Article 15 DISPUTE RESOLUTION

15.1 Deadlock Resolution. In the event a deadlock occurs with respect to the decision-making process of the JSC, such deadlock shall be subject to binding determination by an expert panel in the Hong Kong Special Administrative Region. The expert panel shall consist of [***] members, [***] of which [***] appointed by each Party and the [***] member shall be selected by the other [***] members (collectively, the “**Experts**”). The panel must be appointed within [***] days of the occurrence of a deadlock event or such longer period as the Parties may agree. Each Expert shall be a person having not less than [***] years’ experience in the area of expertise in the business of pharmaceuticals (including biologics) and having no conflict of interest with either Party. If the issues in dispute involve scientific, technical or commercial matters, the Experts chosen hereunder shall have educational training or industry experience sufficient to demonstrate a reasonable level of relevant scientific, medical and industry knowledge, as necessary to resolve the dispute. With respect to any dispute to be submitted to an Expert pursuant to this Agreement, the use of the Expert shall be the exclusive remedy of the Parties, and neither Party shall attempt to adjudicate such dispute in any other forum. The decision of the Experts shall be final and binding on the applicable Parties involved in such dispute and deadlock resolution procedure contemplated by this Section 15.1 and shall not be capable of challenge, whether by arbitration, in court or otherwise. All proceedings and communications shall be in English.

15.2 Disputes. Subject to Sections 15.4 and 15.5, upon the written request of either Party to the other Party, any differences, claim, dispute, or controversy as to the breach, enforcement, interpretation or validity of this Agreement (a “**Dispute**”) shall be referred to the Executive Officers for resolution. In the event such executives are unable to resolve such Dispute within [***] days after the initial written request, then, upon the written demand of either Party and subject to Section 15.4 below, the Dispute shall be referred to and finally resolved by binding arbitration administered by the Hong Kong International Arbitration Centre (“**HKIAC**”) (or any successor entity thereto) pursuant to the United Nations Commission on International Trade Law (“**UNCITRAL**”) Arbitration Rules in force when the notice of arbitration is submitted, as modified by the HKIAC Procedures for the Administration of Arbitration under the UNCITRAL Arbitration Rules (the “**Rules**”), as modified by Section 15.3 below.

15.3 Arbitration.

(a) **Procedure.** The arbitration shall be conducted by a panel of three arbitrators experienced in the business of pharmaceuticals (including biologics). If the issues in dispute involve scientific, technical or commercial matters, the arbitrators chosen hereunder shall engage experts having educational training or industry experience sufficient to demonstrate a reasonable level of relevant scientific, medical and industry knowledge, as necessary to resolve the dispute. Within [***] days after initiation of arbitration, each of the Parties shall select one arbitrator and these two arbitrators shall jointly select a third arbitrator. If a Party fails to select an arbitrator or if the two arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator within such [***] day period, any unselected arbitrator or third arbitrator, as the case may be, shall be appointed in accordance with the Rules. The place of arbitration and the seat of arbitration shall be Hong Kong Special Administrative Region, and all proceedings and communications shall be in English. Unless agreed by the Parties in writing, all documents provided under or in connection with this Agreement shall be in the English language or accompanied by a certified English translation. If such document is translated into any other language, the English language version shall prevail unless the document is a constitution, statutory or other official document. The laws governing this arbitration agreement shall be the laws of

Hong Kong Special Administrative Region and the arbitral award shall be final and binding on the Parties. Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor the arbitrators may disclose the existence, content, or results of arbitration without the prior written consent of both Parties.

(b) **Arbitrators' Award.** The arbitrators shall, within [***] days after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the arbitrators shall be final and non-appealable, and judgment may be entered upon it in any court of competent jurisdiction.

(c) **Costs.** Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators; provided, however, that the arbitrators shall be authorized to determine whether a Party is the prevailing party, and if so, to award to that prevailing party reimbursement for any or all of its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, etc.), and/or the fees and costs of the HKIAC and the arbitrators.

(d) **Protective Orders.** At the request of either Party, the tribunal shall enter an appropriate protective order to maintain the confidentiality of information produced or exchanged in the course of the arbitration proceedings.

15.4 [***]

15.5 Interim Relief. Each Party shall be entitled to take action in any court with competent jurisdiction to apply for and be granted emergency or other interim relief and otherwise enforce by injunction, specific performance or other equitable relief, without prejudice to any other rights and remedies that it may have under this Agreement

15.6 Continued Performance. Provided that this Agreement has not been terminated in its entirety, the Parties agree to continue performing under this Agreement in accordance with its provisions, pending the final resolution of any Dispute.

Article 16 MISCELLANEOUS

16.1 Rights in Bankruptcy.

(a) The Parties intend to take advantage of the protections of Section 365(n) (or any successor provision) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction to the maximum extent permitted by Applicable Law. All rights and licenses granted under or pursuant to this Agreement, but only to the extent they constitute licenses of a right to "intellectual property" as defined in Section 101 of the U.S. Bankruptcy Code or in any analogous provisions in any other country or jurisdiction (as the case may be) shall be deemed to be "intellectual property" for the purposes of Section 365(n) or any analogous provisions in any other country or jurisdiction (as the case may be). The Parties shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, including the right to obtain the intellectual property from another entity.

(b) In the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party that is not subject to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) all such intellectual property (including all embodiments of such intellectual property), which, if not already in the non-subject Party's possession, shall be promptly delivered to it upon the non-subject Party's written request (i) upon commencement of a bankruptcy proceeding, unless the Party subject to such proceeding continues to perform all of its obligations under this Agreement, or (ii) if not delivered pursuant to clause (i) above because the subject Party continues to perform, upon the rejection of this Agreement by or on behalf of the subject Party.

(c) Unless and until the subject Party rejects this Agreement, the subject Party shall perform this Agreement or provide the intellectual property (including all embodiments of such intellectual property) to the non-subject Party, and shall not interfere with the rights of the non-subject Party to such intellectual property, including the right to obtain the intellectual property from another entity.

16.2 Governing Law. This Agreement and any disputes, claims, or actions related thereto shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflicts of law provisions thereof.

16.3 Entire Agreement; Amendment. This Agreement, including the Schedules hereto, sets forth all of the agreements and understandings between the Parties with respect to the subject matter hereof and thereof, and supersedes and terminates all prior agreements and understandings between the Parties with respect to the subject matter hereof and thereof. There are no other agreements or understandings with respect to the subject matter hereof, either oral or written, between the Parties. Except as expressly set forth in this Agreement, no subsequent amendment, modification or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.

16.4 Further Assurances. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as any other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

16.5 Relationship Between the Parties. The Parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship or legal entity of any type between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever. Neither Party shall treat or report the relationship arising under this Agreement as a partnership for United States tax purposes unless otherwise required pursuant to a determination within the meaning of Section 1313 of the Internal Revenue Code of 1986, as amended.

16.6 Non-Waiver. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and of a particular scope, and shall be signed by such Party.

16.7 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned by a Party without the prior written consent of the other Party (which shall not be unreasonably withheld, conditioned or delayed), except to (a) an Affiliate; provided that this Agreement shall be assigned in whole, and the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate; (b) a Third Party in connection with the sale of all or substantially all of its assets to which this Agreement relates, whether in a sale of stock, sale of assets, business combination, reorganization, or other transaction or series of related transactions. Unless expressly stated otherwise in this Agreement, Duality may assign without the prior consent of Licensee its right to receive payments under this Agreement or grant any security interest in its rights, title and interest in this Agreement, in whole or in part and in their entirety or in portions, to an institutional financier in connection with a financing transaction; provided that Duality has given Licensee a prior written notice regarding such assignment. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the permitted assigns of the Parties. Any assignment not in accordance with this Agreement shall be void.

16.8 Third Party Beneficiaries. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including any third party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby.

16.9 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part. The Parties shall use their commercially reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) in a way that, to the extent practicable and legally permissible, implements the original intent of the Parties.

16.10 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by any method of mail (postage prepaid) requiring return receipt, or by overnight courier or facsimile confirmed thereafter by any of the foregoing, to the Party to be notified at its address(es) given below, or at any address such Party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; (b) if delivered by overnight courier, [***] Business Days after delivery; or (c) if sent by facsimile, upon electronic confirmation of receipt.

if to Duality:

Duality Biologics (Suzhou) Co., Ltd
Unit 1106, No 868 Yinghua Road, Pudong New District, Shanghai,
China
Attention: [***]

Email: [***]

[***]

[***]
[***]
[***]
[***]
[***]
[***]

if to Licensee:

BIONTECH SE
[***]
Address: An der Goldgrube 12,
55131 Mainz,
Germany

with a copy to:

[***]

16.11 Force Majeure. Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such Party’s reasonable control including but not limited to acts of God, fire, flood, explosion, earthquake, or other natural forces, regional or worldwide epidemic, pandemic, war, civil unrest, acts of terrorism, accident, destruction or other casualty, and a material change in Applicable Law (a “**Force Majeure Event**”). Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused such event(s) to occur. Notice of a Party’s failure or delay in performance due to a Force Majeure Event must be given to the other Party within [***] days after its occurrence. The Party affected by a Force Majeure Event will use reasonable efforts to resume performance of its obligations and will keep the other Party informed of actions related thereto. If any such failure or delay in a Party’s performance hereunder continues for more than [***] days, the other Party may terminate this Agreement upon written notice to the delayed Party.

16.12 Interpretation. The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. The words

“include”, “including”, “containing”, “comprising” and similar words shall not be deemed to be terms of limitation and shall be deemed to be followed by “without limitation,” whether or not specifically stated and the language following such words shall not be deemed to set forth an exhaustive list. The word “or” means “and/or” unless the context dictates otherwise because the subject of the conjunction are mutually exclusive. The words “herein,” “hereof” and “hereunder” and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. The words “pharmaceuticals” or “drugs” include biologics unless expressly indicated otherwise. All references to days in this Agreement shall mean calendar days, unless otherwise specified. All references to any Applicable Law in this Agreement shall mean such Applicable Law as amended, restated, supplanted or otherwise modified from time to time. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist.

16.13 Construction. The Parties hereto acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in a favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

16.14 Counterparts; Electronic Signatures. This Agreement may be executed in two (2) or more counterparts, including by transmission of facsimile or PDF copies of signature pages to the Parties or their representative legal counsel, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one and the same instrument. Electronic, facsimile or PDF image signatures shall be treated as original signatures, with the understanding that each Party expressly agrees that such Party shall be bound by its own electronically transmitted signature and shall accept the electronically transmitted signature of the other Party (including through the use of eSignature platforms such as DocuSign®). No Party will raise the use of electronic delivery to transmit a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of electronic delivery as a defense to the formation of a contract.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

In Witness Whereof, the Parties hereto have duly executed this **License and Collaboration Agreement** as of the Effective Date.

Duality Biologics (Suzhou) Co., Ltd.

By: /s/ Zhongyuan John Zhu
Name: Zhongyuan John Zhu
Title: Chief Executive Officer

BioNTech SE

By: /s/ Uğur Sahin
Name: Ugur Sahin
Title: Chief Executive Officer

By: /s/ Sean Marett
Name: Sean Marett
Title: Chief Business Officer and Chief Commercial Officer

Signature Page to Trop2 License And Collaboration Agreement

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Schedule 1.1

ABC Terms

1. Each Party agrees that it will not undertake any activities which will result in a violation of any applicable laws, regulations, and applicable industry and professional codes, including but not limited to applicable local and extraterritorial anti-bribery, Anti-Corruption Laws and anti-money laundering laws (collectively "**Prohibited Conduct**") in connection with the performance of any activities under this Agreement.
2. In particular, each Party agrees that during the course of the performance of activities under this Agreement, it (i) shall not make any offer, payment, or promise to pay money or provide anything of value to a Government Official (as defined below) or any other individual and/or legal entity whether directly or indirectly, for the purpose of improperly influencing any act and/or decision of, and/or for securing any improper advantage; (ii) shall not accept, receive, agree to accept and/or receive a payment and/or anything of value from any individual for undue favorable treatment in obtaining, retaining, and/or directing business for, and/or to obtain any undue special concession on behalf of either Party; and (iii) shall not facilitate any payments to any Government Official to expedite a routine government action and/or other official act.
3. The term "**Government Official**" shall include (i) individuals acting on behalf of governments on a national, regional and local level (such as elected officials, customs officials, tax officials, etc.); (ii) individuals acting on behalf of government-owned or government-controlled enterprises; (iii) individuals acting for political parties or as or on behalf of candidates for public office; and (iv) individuals acting on behalf of public international organizations (such as the WHO, World Bank, OECD, etc.).
4. All transactions and expenses incurred on behalf of either Party shall be accurately recorded and maintained in the respective Party's books and records in a timely manner and in reasonable detail in accordance with the applicable generally accepted accounting principles. False, misleading, incomplete, duplicated, inaccurate or artificial entries for the foregoing expenses in a Party's books and records are strictly prohibited.
5. Each Party agrees that if it becomes aware or has reason to suspect that any person or legal entity acting on the Party's and/or the other Party's behalf has engaged in any Prohibited Conduct related to the Agreement, then such Party will promptly report such knowledge or suspicion to the other Party via the following email address: (a) in case that Duality is the reporting party: [***] and (b) in case that Licensee is the reporting party: [***].
6. Duality shall apply Commercially Reasonable Efforts to implement, operate and enforce, without undue delay after the Effective Date, a reasonably designed compliance and business

ethics management and control system that is intended for the prevention and detection of criminal conduct in accordance with applicable Anti-Corruption Laws.

7. Each Party agrees to provide reasonable cooperation in any investigation that may be conducted by or on behalf of the other Party related to the performance of potentially Prohibited Conduct as described in Article 1 above. Upon notice of an intended investigation, a Party will provide, in a reasonable time, to the investigating Party or to a third party engaged by the investigating Party: (a) access to the relevant persons; and/or (b) access to relevant documents and data (e.g., invoices and requests for expense reimbursement, supporting receipts and substantiation, and original entry records for charges and payments).
8. Each Party acknowledges that the obligations under the applicable local and extraterritorial anti-bribery, Anti-Corruption Laws and anti-money laundering laws apply to all its Affiliates and employees, subcontractors and Sublicensees (in case of Licensee) or sublicensees (in case of Duality). Each Party will bind subcontractors who act for or on behalf of such Party to perform activities under this Agreement by such Party for or on behalf of the other Party by respective contractual clauses encompassing all or all material provisions of this Schedule.

Schedule 1.54
Duality In-Licensed Agreements

[***]

Schedule 1.57

Description of Duality Know-How

[***]

Schedule 1.63
List of Duality Patent Rights

[***]

Schedule 1.94
List of Indications

[***]

Schedule 1.102
Licensed Compound

[***]

Schedule 1.141
Original ADC Licensed Product
Preliminary Development Plan as of the Effective Date

[***]

[***]

[***]

[***]

[***]

Schedule 1.149
Pre-clinical Proof-of-Concept Criteria

[***]

Schedule 2.6
Initial Know-How Transfer

[***]

Schedule 9.2
Invoicing Procedures & Invoice Information

[***]

Schedule 10.4
Duality Press Release

[***]

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Schedule 11.2
Disclosure Schedule

[***]

*** Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) the type of information that the Registrant treats as private or confidential.

Execution Version

Dated 26 October 2023

BIOTHEUS INC. (普米斯生物技术(珠海)有限公司) (1)

AND

BIONTECH SE (2)

COLLABORATION, LICENSE AND OPTION AGREEMENT

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COLLABORATION, LICENSE AND OPTION AGREEMENT

This **COLLABORATION, LICENSE AND OPTION AGREEMENT** (this "**Agreement**") is entered into this 26th day of October, 2023 (the "**Execution Date**"), by and between

- (1) **BIOTHEUS INC.** (in Chinese: 普米斯生物技术(珠海)有限公司), a limited company incorporated in the People's Republic of China (Unified Social Credit Code: 91440400MA51YKAW2M), having its registered office at Unit 10-B, Building 4, No. 1, Keji 7th Road, Tangjiawan Town, High-Tech Zone, Zhuhai City, Guangdong Province, the People's Republic of China ("**Biotheus**"); and
- (2) **BIONTECH SE**, a company incorporated in Germany having its registered office at An der Goldgrube 12, D-55131 Mainz, Germany ("**BioNTech**").

Biotheus and BioNTech are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

- (A) WHEREAS, Biotheus is a biopharmaceutical company focused on the discovery and development of novel drugs to treat cancer and inflammatory diseases;
- (B) WHEREAS, BioNTech is a German biotechnology company based in Mainz focused on the development and manufacture of active immunotherapies for patient-specific approaches to the treatment of diseases;
- (C) WHEREAS, BioNTech desires to obtain from Biotheus an exclusive license with respect to PM8002 Licensed Products under the applicable Licensed Patent Rights and the applicable Licensed Know-How to Develop, Manufacture and Commercialize PM8002 Licensed Products in the Field in the Territory, under the terms and conditions set forth herein, and Biotheus desires to grant to BioNTech such license with respect to PM8002 Licensed Products, while Biotheus retains the right to Develop, Manufacture and Commercialize PM8002 Licensed Products in the Retained Territory in close coordination with BioNTech;
- (D) WHEREAS, BioNTech desires to obtain options to an exclusive license with respect to PM8003 Licensed Products and Preclinical Multispecific Licensed Products under the terms and conditions set forth herein, and Biotheus desires to grant such options.

NOW, THEREFORE, the Parties agree as follows:

1 DEFINITIONS

The following terms, whether used in the singular or plural, will have the following meanings:

- | | | |
|-----|------------------------------|--|
| 1.1 | 1st line HCC/CRC/PROC | means First Line Hepatocellular carcinoma / Colorectal Cancer/Platinum Resistant Ovarian Cancer; |
| 1.2 | 1st line nccRCC | means First Line non clear cell renal cell carcinomas; |
| 1.3 | 1st line SCLC | means First Line Small Cell Lung Cancer; |
| 1.4 | 1st line TNBC | means First Line Triple Negative Breast Cancer; |
| 1.5 | 2nd line NSCLC | means Second Line Non Small Cell Lung Cancer; |
| 1.6 | 2nd line RCC | means Second Line renal cell carcinoma; |
| 1.7 | 2nd line SCLC | means Second Line Small Cell Lung Cancer; |
| 1.8 | Accelerated Approval | means drugs for serious conditions that fill an unmet medical need approved based on a surrogate endpoint as defined by FDASIA Section 901 and 21 CFR 314 Subpart H; |

- 1.9 **Accounting Standards** means (a) with respect to BioNTech, its Affiliates or their respective Sublicensees, International Financial Reporting Standards as issued by the International Accounting Standards Board and endorsed by the EU, consistently applied or any other applicable standard accounting principles used by Sublicensees; and (b) with respect to Biotheus, Accounting Standards for Business Enterprises as promulgated by Chinese Accounting Standards Committee of Ministry of Finance of the People's Republic of China or its successor organization or any other applicable standard accounting principles used by the applicable Affiliates of Biotheus;
- 1.10 **ADC** means [***];
- 1.11 **Additional Third Party Licences** has the meaning set forth in Section 8.5(b) (Adjustments to Royalties);
- 1.12 **Affiliate** means, with respect to any Person, any Person controlling, controlled by or under common control with such Person. For the purposes of this Section 1.12 (Affiliate), the term "control" (including, with correlative meaning, the terms "controlled by" and "under common control with"), means the possession, directly or indirectly, of more than 50% of the voting stock or other ownership interest of such Person, or the possession, directly or indirectly, of the power to direct or cause the direction of the affairs or management and policies of such Person or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of such Person. The Parties acknowledge that in the case of certain entities organised under the laws of certain countries outside the United States, the maximum percentage ownership permitted by Applicable Law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage will be substituted in the preceding sentence; provided that such foreign investor has the power to direct the management and policies of such entity;
- 1.13 **Agreement** has the meaning set forth in the Preamble;

- 1.14 **Alliance Manager** has the meaning set forth in Section 4.3 (Alliance and Project Managers);
- 1.15 **Antibody** means

[***];
- 1.16 **Anti-Corruption Laws** means all applicable anti-bribery and anti-corruption laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, the U.K. Bribery Act 2010, and the comparable Applicable Laws of any countries in which Licensed Products, payments or services will be provided or procured under or pursuant to this Agreement;
- 1.17 **Applicable Data Protection Law** means all Applicable Laws in any jurisdiction relating to privacy or the processing or protection of personal data or personal information, including the General Data Protection Regulation (EU) 2016/679 (GDPR), the UK Data Protection Act 2018, the e-Privacy Directive (2002/58/EC) and the comparable in other jurisdictions and all guidance issued by any applicable data protection authority;
- 1.18 **Applicable Law** means any law, statute, rule, regulation, order, judgment, ordinance or guidance of any Governmental Authority, including all applicable GxPs, Anti-Corruption Laws, Applicable Data Protection Laws, accounting and recordkeeping laws, and laws relating to interactions with healthcare professionals and Government Officials. For the avoidance of doubt, any specific references to any Applicable Law or any portion thereof shall be deemed to include all then-current amendments thereto or any replacement or successor law, statute, standard, ordinance, code, rule, regulation, resolution, promulgation, order, writ, judgment, injunction, decree, stipulation, ruling, guidance or determination thereto;

1.19	Audited Party	has the meaning set forth in Section 8.12(a) (Books and Records);
1.20	Auditing Party	has the meaning set forth in Section 8.12(a) (Books and Records);
1.21	Auditor	has the meaning set forth in Section 8.12(a) (Books and Records);
1.22	Bankrupt Party	has the meaning set forth in Section 13.2(d) (Termination for Bankruptcy);
1.23	Bankruptcy Code	has the meaning set forth in Section 14.15 (Rights in Bankruptcy);
1.24	BioNTech	has the meaning set forth in the Preamble;
1.25	BioNTech Background IP	means BioNTech Background Know-How and BioNTech Background Patent Rights;
1.26	BioNTech Background Know-How	means the Know-How that is Controlled by BioNTech or its Affiliates (a) as of the Effective Date or (b) during the Term other than pursuant to Section 3.1 (License Grants to BioNTech) of this Agreement that, in each case (a) and (b) is necessary or useful for the Development of the applicable Licensed Products in the Field in the Territory in accordance with the Global CDP and Joint CDP. A description of BioNTech Background Know-How as of the Execution Date is set out in Schedule 5 and such Schedule may be updated by agreement of the JSC from time to time;
1.27	BioNTech Background Patent Rights	means the Patent Rights Controlled by BioNTech or its Affiliates as of the Effective Date or during the Term that claim or Cover any BioNTech Background Know-How;

- 1.28 **BioNTech Competing Products** means [***];
- 1.29 **BioNTech Competitor** means the Persons listed in Schedule 7 as such list may be updated by BioNTech from time to time;
- 1.30 **BioNTech Retained Territory Competitor** means [***];
- 1.31 **BioNTech Foreground IP** means the BioNTech Foreground Know-How and BioNTech Foreground Patent Rights;
- 1.32 **BioNTech Foreground Know-How** means [***];
- 1.33 **BioNTech Foreground Patent Rights** means any and all Patent Rights that claim or Cover BioNTech Foreground Know-How;
- 1.34 **BioNTech Indemnitees** has the meaning set forth in Section 12.2 (Indemnification of BioNTech by Biotheus);
- 1.35 **BioNTech Multispecific Antibody** means a Licensed Product that is a Multispecific Antibody [***];
- 1.36 **BioNTech-Prosecuted Patent Rights** has the meaning set forth in Section 9.2(d) (BioNTech-Prosecuted Patent Rights);
- 1.37 **Biosimilar Product** means, [***];
- 1.38 **Biotheus** has the meaning set forth in the Preamble;
- 1.39 **Biotheus Background IP** means the Patent Rights and Know-How relating to Biotheus' proprietary platform technology and set out or described in Schedule 6. Such Schedule may be updated by agreement of the Joint IP Committee from time to time;

1.40	Biotheus Foreground IP	means the Biotheus Foreground Know-How and Biotheus Foreground Patent Rights;
1.41	Biotheus Foreground Know-How	means [***];
1.42	Biotheus Foreground Patent Rights	means any and all Patent Rights that claim or Cover Biotheus Foreground Know-How;
1.43	Biotheus Indemnitees	has the meaning set forth in Section 12.1 (Indemnification of Biotheus by BioNTech);
1.44	Biotheus In-Licenses	means any agreement between Biotheus and a Third Party pursuant to which Biotheus or its Affiliates Controls the Licensed IP, as set forth in Schedule 8A;
1.45	Biotheus Platform Foreground IP	means [***];
1.46	Biotheus Platform Foreground Know-How	means [***];
1.47	Biotheus Foreground Patent Rights	means any and all Patent Rights that claim or Cover Biotheus Foreground Know-How;
1.48	Biotheus-Prosecuted Patent Rights	has the meaning set forth in Section 9.2(e) (Biotheus-Prosecuted Patent Rights);
1.49	[***]	[***]
1.50	Bispecific Antibody	means [***];
1.51	Bispecific Licensed Product	means [***];
1.52	Bispecific Patent Right	means [***];

- 1.53 **BLA** means an application filed with the FDA or applicable Regulatory Authorities outside the United States for approval to commercially market, import and sell a biological product;
- 1.54 **Breakthrough Designation** means a drug as defined by FDASIA Section 902 that: (a) intended alone or in combination with one or more other drugs to treat a serious or life threatening disease or condition and (b) preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development;
- 1.55 **Business Day** means a day that is not a Saturday, Sunday, or a day on which banking institutions in Mainz, Germany, Hong Kong, and Zhuhai, China are authorized or required by Applicable Law to remain closed;
- 1.56 **Calendar Quarter** means each period of three consecutive calendar months ending on March 31, June 30, September 30, or December 31, except that the first Calendar Quarter of the Term will commence on the Effective Date, and the last Calendar Quarter of the Term will end on the effective date of the termination or expiration of this Agreement;
- 1.57 **Calendar Year** means each period of twelve (12) consecutive calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term will commence on the Effective Date, and the last Calendar Year of the Term will end on the effective date of the termination or expiration of this Agreement;
- 1.58 **C.F.R.** means the U.S. Code of Federal Regulations;

- 1.59 **cGCP** means any and all laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the ethical conduct of clinical trials, including without limitation the U.S. Code of Federal Regulations (CFR) Title 21, ICH GCP Guidelines E6(R2) as amended from time to time, national legislation implementing European Community Directive 2001/20/EC (if and as still applicable), European Community Directive 2005/28/EC, and, following the applicable transition periods, the Clinical Trial Regulation (EU) No. 536/2014 (the "CTR") and the rules, regulations and guidelines applying in the context of the CTR, China Good Clinical Practice Rules and the equivalent in other countries or regions;
- 1.60 **cGLP** means any and all laws, rules, regulations, guidelines and generally accepted standards and requirements regarding quality control for laboratories to ensure the consistency and reliability of results, including without limitation the CFR Title 21, national legislation implementing European Community Directives 2004/9/EC and 2004/10/EC as amended, and the OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, China Drug Good Laboratory Practice Rules (China Non-Clinical Research Quality Management Standard) and the equivalent in other countries or regions. For the purposes of this Agreement, GLP also includes the principles of "Good Clinical Laboratory Practice" which means any and all laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the treatment of human laboratory samples from Clinical Trials, including the relevant principles from GCP and the EMA's reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples, as amended from time to time;

1.61	cGMP	means any and all laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the quality control and manufacturing of pharmaceutical products, including without limitation the CFR Title 21, Parts 11, 210, 211, 600 and 610, applicable ICH Guidelines including without limitation Q7 for "Active Pharmaceuticals Ingredients", national legislation implementing European Community Directive 2001/83/EC and Commission Directive 2003/94/EC as amended, EudraLex – Volume 4 of the Rules Governing Medicinal Products in the European Union including annexes, the CTR, Commission Delegated Regulation 2017/1569, the Detailed Commission Guideline (2017) 8179, and the equivalent in other countries or regions including in China;
1.62	cGood Pharmacovigilance Practice or cGVP	means the current Good Pharmacovigilance Practices applicable to the conduct of specific pharmacovigilance activities, including US Code of Federal Regulations ("CFR") Title 21 covering US Food and Drug Administration ("FDA") regulations ("FDA 21 CFR"), as amplified by relevant FDA guidance, Compliance guides, and other relevant regulatory materials, International Council on Harmonisation ("ICH") of Technical Requirements for Registration of Pharmaceuticals for Human Use (Codes, E2A, E2B, E2C, E2D), European Union ("EU") regulations and directives and/or local regulations, China Good Pharmacovigilance Practice Rule (China Pharmacovigilance Quality Management Standard).in each case as applicable;
1.63	China	means the People's Republic of China (including mainland China, Hong Kong, Macau and Taiwan);
1.64	Claim	has the meaning set forth in Section 14.1(a) (Escalation);
1.65	Clinical Trial	means [***];
1.66	CMC	means chemistry, manufacturing and controls;
1.67	[***]	[***]

- 1.68 **Combination Product** means [***]. Each such additional [***] shall be "an Other Component";
- 1.69 **Commercialization or
Commercialize** means activities related to the commercialization of a product, including the pre-marketing, launching, marketing, promotion (including advertising and detailing), market research, labeling, bidding and listing, market access activities, pricing and reimbursement, distribution, storage, handling, Manufacturing for commercial sale (including inventory build to support launch), offering for sale, selling, having sold, importing and exporting for sale, having imported and exported for sale, distribution, having distributed, order processing, handling returns and recalls, customer service and support, and post-marketing safety surveillance and reporting of a product, medical affairs and medical science liaison activities, as well all regulatory compliance and conduct of administrative functions with respect to the foregoing. For clarity, "Commercialization" includes all pre-launch marketing and other launch preparation activities, including training of personnel who will conduct Commercialization activities, as well as manufacturing activities in preparation for and to establish and maintain commercial sales. When used as a verb, "Commercialize" means to engage in Commercialization;
- 1.70 **Commercially Reasonable Efforts** [***]
- 1.71 **Competitive Infringement** has the meaning set forth in Section 9.3(a) (Notification);

1.72 **Confidential Information**

means:

- (a) the existence and terms of this Agreement; and
- (b) with respect to each Party, Know-How, inventions, Materials, and other proprietary information including data and all other scientific, pre-clinical, clinical, regulatory, Manufacturing, marketing, financial and commercial information or data that is disclosed, made available to, or provided by or on behalf of such Party to the other Party or to any of the Receiving Party's employees, consultants, Affiliates, or Sublicensees, whether or not specifically marked or designated by the Disclosing Party as confidential;

Notwithstanding the foregoing, Confidential Information constituting:

- (a) [***] Background Know-How and [***] Foreground Know-How shall be considered Confidential Information [***];
- (b) subject to Section 10.3 (Publications and Presentations), Licensed Know-How shall be considered Confidential Information [***] PROVIDED THAT Product-Specific Know-How shall, during the Term be deemed to be the Confidential Information [***];
- (c) Joint Know-How shall be the Confidential Information of both Parties (and both Parties shall be the Receiving Party and the Disclosing Party with respect thereto); and
- (d) the existence, scope and terms and conditions of this Agreement shall be the Confidential Information of both Parties (and both Parties shall be the Receiving Party and the Disclosing Party with respect thereto).

For clarity, (i) specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party; and (ii) any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party;

1.73	Confidentiality Agreement	has the meaning set forth in Section 10.1(b) (Confidential Information of Each Party);
1.74	Control or Controlled	<p>means the possession by a Party (whether by ownership, license or otherwise, other than pursuant to this Agreement) of:</p> <p>(a) with respect to any materials or other tangible Know-How, the legal authority or right to physical possession of such materials or tangible Know-How, with the right to provide such materials or tangible Know-How to the other Party on the terms set forth herein;</p> <p>(b) with respect to Patent Rights, Regulatory Authorizations, Regulatory Filings, intangible Know-How or other intellectual property, the legal authority or right to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patent Rights, Regulatory Authorizations, Regulatory Filings, intangible Know-How or other intellectual property on the terms set forth herein;</p> <p>in each case (a) and (b), without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, license, or sublicense;</p>
1.75	Cost of Goods	means, [***];
1.76	Cover, Covers, or Covered	means, [***];
1.77	Development or Develop	<p>means, with respect to any product, any and all internal and external research, development, pharmacovigilance activities, and regulatory activities regarding such product, including:</p> <p>(a) research, process development, non-clinical testing, toxicology, non-clinical activities, IND-enabling studies, and Clinical Trials, and</p> <p>(b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain, support, or maintain Regulatory Authorization of such product, but excluding any activities directed to Manufacturing or Commercialization. Development will include research, development, and regulatory activities for additional presentations or Indications for a product after receipt of Regulatory Authorization of such product, including Clinical Trials initiated following receipt of Regulatory Authorization or any Clinical Trial to be conducted after receipt of Regulatory Authorization that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Authorization with respect to an approved Indication (such as post-marketing approval studies and observational studies, if required by any Regulatory Authority in any country in the Territory to support or maintain Regulatory Authorization for a product in such country). "Develop", "Developing" and "Developed" will be construed accordingly;</p>
1.78	Development Milestone Event	has the meaning set forth in Section 8.3 (Development and Approval Milestone Payments for Licensed Products);
1.79	Development Milestone Payment	has the meaning set forth in Section 8.3 (Development and Approval Milestone Payments for Licensed Products);
1.80	Directed	means, [***];

- 1.81 **Disclosing Party** has the meaning set forth in Section 10.1(a) (General);
- 1.82 **Effective Date** means with respect to this Agreement the date of the expiration or termination of any applicable waiting period under the HSR Act;
- 1.83 **Eligible Development Costs** means, [***];

1.84	EMA	means the European Medicines Agency or any successor agency or authority thereto;
1.85	European Union or EU	means all countries or territories that are officially part of the European Union, as constituted from time to time;
1.86	Executive Officer	has the meaning set forth in Section 14.1(a) (Escalation);
1.87	Exploit	means Develop, have Developed, make, have made, use, have used, perform medical affairs, have performed medical affairs, offer for sale, have offered for sale, sell, have sold, export, have exported, import, have imported, Manufacture, have Manufactured, Commercialize or have Commercialized. "Exploitation" and "Exploiting" will be construed accordingly;
1.88	Extensions	has the meaning set forth in Section 9.2(h) (Patent term extension and supplementary protection certificates);
1.89	External Expenses	means documented expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with Accounting Standards) by a Party (or its Affiliate) in the performance of activities under this Agreement, including capital expenditures that are specifically allocated to such activities and travel expenses incurred for carrying out such activities, but excluding financing costs;
1.90	FDA	means the United States Food and Drug Administration and any successor agency or authority thereto;
1.91	FD&C Act	means the United States Food, Drug, and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder, as may be in effect from time to time;

1.100	Global Commercialization Strategy	has the meaning set forth in Section 5.1(a) (Global Commercialization Strategy);
1.101	Global Trial	has the meaning set forth in Section 5.3(a) (Global CDP);
1.102	Governmental Approval	has the meaning set forth in Section 11.3(f) (Biotheus Covenants);
1.103	Government or Governmental Authority	means (a) any national, federal, state, local, provincial, regional or foreign government, or level, ranch, or subdivision thereof; (b) any multinational or public international organization or authority; (c) any ministry, department, bureau, division, authority, agency, commission, or body entitled to exercise any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power; (d) any court, tribunal, or governmental arbitrator or arbitral body; (e) any government-owned or controlled institution or entity; (f) any enterprise or instrumentality performing a governmental function; (g) any political party, and (h) any Regulatory Authority;
1.104	Government Official	means (a) any elected or appointed government official (e.g., a member of a ministry of health), (b) any employee or person acting for or on behalf of a government official, Governmental Authority, or other enterprise performing a governmental function, (c) any political party, candidate for public office, officer, employee, or person acting for or on behalf of a political party or candidate for public office, (d) any member of a military or a royal or ruling family, and (e) any employee or person acting for or on behalf of a public international organization (e.g., the United Nations). For clarity, healthcare providers employed by Government-owned or -controlled hospitals, or a person serving on a healthcare committee that advises a Government, will be considered Government Officials. In addition, all healthcare providers in a given country will be considered Government Officials where this is required by Applicable Law;

1.105	GxP	means, collectively, all relevant good practice quality guidelines and regulations and related implementation guidelines, encompassing such internationally recognized standards as cGCP, cGMP, cGLP, cGVP;
1.106	HSR Act	means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, codified at 15 U.S.C. § 18a, as may be amended from time to time, and the rules and regulations promulgated thereunder, or foreign equivalent thereof under Applicable Law (including all additions, supplements, extensions and modifications thereto);
1.107	IFRS	means, at any time, the International Financial Reporting Standards promulgated by the International Accounting Standards Board, as amended, supplemented, or replaced from time to time and as endorsed by the European Union;
1.108	Investigational New Drug Application or IND	means, an Investigational New Drug application in the US filed with the FDA or an analogous application or submission with any analogous Regulatory Authority in other countries / regions / regulatory jurisdictions for the purposes of obtaining permission to conduct Clinical Trials, including Clinical Trial applications submitted to Regulatory Authorities in the EU via the CTIS;
1.109	Improved Licensed Product	means a Licensed Product that is [***]. For clarity, a Preclinical Multispecific Licensed Product shall not be deemed to be an Improved Licensed Product;
1.110	Improved Licensed Product Conditions	has the meaning set forth in Section 3.7 (BioNTech Exclusivity and Improved Licensed Product Conditions);

1.111	Indemnatee	has the meaning set forth in Section 12.3 (Conditions to Indemnification);
1.112	Indication	means, [***];
1.113	Indirect Taxes	means value added, sales, consumption, goods, and services taxes or other similar taxes required by Applicable Law to be disclosed as a separate item on the relevant invoice;
1.114	Infringement	has the meaning set forth in Section 9.3(a) (Notification);
1.115	Infringement Action	has the meaning set forth in Section 9.3(b) (Infringement Actions);
1.116	In-Licensed BioNTech Products	means any compound or product the rights to which are owned by a Third Party and either as at the Effective Date or during the Term are licensed to or otherwise acquired by BioNTech or its Affiliates;
1.117	Intellectual Property Rights	means any Know-How, Patent Rights, Trademarks, copyrights, trade secrets, and any other intellectual property rights however denominated throughout the world;
1.118	Interest Rate	has the meaning set forth in Section 8.14 (Late Fees);
1.119	Internal Costs	means, for any period, the product obtained by multiplying: <ul style="list-style-type: none"> (a) the actual total FTEs (or portion thereof) devoted to the performance of an activity under this Agreement during such period, by (b) the applicable FTE Rate;

1.120	Invention	means any invention, discovery, or Know-How that is discovered, generated or conceived by or on behalf of a Party or its Affiliate or Sublicensee in the performance of activities under this Agreement;
1.121	JCWG	has the meaning set forth in Section 5.1(b) (Formation of Joint Commercialization Working Group);
1.122	Joint CDP	has the meaning set forth in Section 5.3(b) (Joint CDP);
1.123	Joint CDP Activities	means the activities to be conducted by the Parties pursuant to the Joint CDP;
1.124	Joint Development and Operations Working Group	has the meaning set forth in Section 4.2(b) (Joint Development and Operations Working Group);
1.125	Joint IP	means all Joint Know-How and Joint Patent Rights;
1.126	Joint IP Committee	has the meaning set forth in Section 4.2(c) (Joint IP Committee);
1.127	Joint Know-How	means [***];
1.128	Joint Patent Rights	means any Patent Rights that Cover or otherwise claim Joint Know-How;
1.129	Joint Steering Committee or JSC	has the meaning set forth in Section 4.1(a) (Formation and Purpose of the JSC);
1.130	Joint Trial	has the meaning set forth in Section 5.3(b) (Joint CDP);

1.135 **Licensed Patent Right**

means the Patent Rights Controlled by Biotheus or any of its Affiliates as of the Effective Date or during the Term (including Patent Rights which Cover or otherwise claim Inventions solely owned by Biotheus pursuant to Section 9.1(a) (Ownership), and including Biotheus' interest in Joint Patent Rights) that are necessary or useful for the Exploitation of any Licensed Products in the Field in the Territory including, but not limited to, the Patent Rights listed in Schedule 3. Notwithstanding the foregoing, Licensed Patent Rights shall not include (i) any Patent Right that is Controlled by any Third Party that acquires more than fifty percent (50%) of the issued share capital of Biotheus and thereby becomes an Affiliate of Biotheus after the Effective Date as a result of a merger, acquisition or other similar transaction, or (ii) any Patent Right that Covers any other proprietary compound, component or product Controlled by Biotheus or any of its Affiliates and is not necessary or useful for the Exploitation of any Licensed Products in the Field in the Territory;

1.136 **Licensed Product**

means any and all of the following:

- (a) a PM8002 Licensed Product;
- (b) a PM8003 Licensed Product, provided that this item (b) shall only become a Licensed Product after the PM8003 Option Exercise Date; or
- (c) a Preclinical Multispecific Licensed Product, provided that this item (c) shall only become a Licensed Product after the Preclinical Multispecific Option Exercise Date.

1.137	*** License	has the meaning set forth in Section 7.2 (Manufacturing Technology Transfer for PM8002 Licensed Products);
1.138	***	***
1.139	Losses	has the meaning set forth in Section 12.1 (Indemnification of Biotheus by BioNTech);
1.140	Major Markets	means ***;
1.141	Manufacture or Manufacturing	means, with respect to a Licensed Product, activities directed to the sourcing and purchasing of materials, producing, manufacturing, processing, compounding, filling, finishing, packing, packaging, labelling, leafleting, quality assurance, quality control testing and release, shipping, storage, and sample retention of such Licensed Product. "Manufacturing" and "Manufactured" will be construed accordingly;
1.142	Manufacturing Technology Transfer	has the meaning set forth in Section 7.2 (Manufacturing Technology Transfer for PM8002 Licensed Products);
1.143	Marketing Authorization or MA	means the authorization by all relevant Regulatory Authorities of a Marketing Authorization Application in a given country or regulatory region / jurisdiction and the granting of the required authorization;
1.144	Marketing Authorization Application or MAA	means an application to a Regulatory Authority for authorization to place a Licensed Product on the market (including Pricing and Reimbursement Approval) in a country, region or a regulatory jurisdiction (including for example an NDA / BLA in the US and the comparable applications in other jurisdictions);

1.145	Materials	means any tangible compositions of matter, articles of manufacture, assays, chemical, biological or physical materials, and other similar materials;
1.146	Multispecific Antibody	means an Antibody that is [***];
1.147	Multispecific Antibody Option	has the meaning set forth in Section 2.2 (Option to Biotheus);
1.148	Multispecific Antibody Option Exercise Date	has the meaning set forth in Section 2.2 (Option to Biotheus);
1.149	Multispecific Antibody Option Exercise Notice	has the meaning set forth in Section 2.2 (Option to Biotheus);
1.150	Multispecific Antibody Option Period	means the period from the [***] with respect to a Licensed Product in the form of a Multispecific Antibody;
1.151	Net Sales	means [***];
1.152	Non-Bankrupt Party	has the meaning set forth in Section 13.2(d) (Termination for Bankruptcy);
1.153	Non-Withholding Party	has the meaning set forth in Section 8.17 (Withholding Taxes);
1.154	Opted-Out Indication	has the meaning set forth in Section 5.6 (Data Sharing);
1.155	Opted-Out Trial	has the meaning set forth in Section 5.6 (Data Sharing);

1.156	Orphan Drug Designation	means a drug intended for use in a rare disease or condition as defined in section 526 of the Federal Food, Drug, and Cosmetic Act as amended by section 2 of the Orphan Drug Act (sections 525–528 (21 U.S.C. 360aa–360dd));
1.157	Other Component	has the meaning set forth in Section 1.68 (Combination Product);
1.158	Outside Date	has the meaning set forth in Section 14.16 (HSR);
1.159	Party	has the meaning set forth in the Preamble;
1.160	***	has the meaning set forth in [***];
1.161	Patent Rights	<p>means all rights, title and interests in and to</p> <p>(a) all national, regional, and international patents and patent applications filed in any country, region or territory of the world including provisional patent applications and all supplementary protection certificates;</p> <p>(b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority to any of the foregoing, including any continuation, continuation-in part, divisional, provisional, converted provisionals and continued prosecution applications, or any substitute applications;</p> <p>(c) any patent issued with respect to or in the future issued from any such patent applications, including utility models, petty patents, design patents and certificates of invention; and</p> <p>(d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, reexaminations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications;</p>
1.162	Payments	has the meaning set forth in Section 8.17 (Withholding Taxes);
1.163	PDL1 Patent Right	means [***];

1.164	Person	means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including any Governmental Authority (or any department, agency, or political subdivision thereof);
1.165	Phase I Clinical Trial	means a Clinical Trial that generally provides for the first introduction into humans of a Licensed Product with the primary purpose of determining initial safety or tolerance, metabolism and PK/PD properties of such product, in a manner that is generally consistent with 21 CFR § 312.21(a), as amended (or its successor regulation);
1.166	Phase II Clinical Trial	means a Clinical Trial, the principal purpose of which is to make a preliminary determination as to whether a pharmaceutical product is safe for its intended use and to obtain sufficient information about such product's efficacy for its intended use (proof of concept) in a manner that is generally consistent with 21 CFR § 312.21(b), as amended (or its successor regulation), to permit the design of further Clinical Trials;
1.167	Phase III Clinical Trial	means a pivotal/registrational Clinical Trial with a defined dose or a set of defined doses of a Licensed Product designed to ascertain efficacy and safety of such Licensed Product, in a manner that is generally consistent with 21 CFR § 312.21(c), as amended (or its successor regulation), for the purpose of enabling the preparation and submission of an application for Regulatory Authorization. This can include Phase IIb Clinical Trials;
1.168	PM8002 Licensed Compound	means [***];
1.169	PM8002 Licensed Product	means [***];

1.170	PM8002 Product-Specific Patent Right	means any Licensed Patent Right (including any Joint Patent Rights) that solely identifies or discloses or solely Covers a PM8002 Licensed Product(s) or its or their use or process of manufacture and does not claim or Cover any proprietary products Controlled by Biotheus other than such PM8002 Licensed Product(s). [***];
1.171	PM8003 Licensed Compound	means Biotheus' [***]
1.172	PM8003 Licensed Product	means, [***];
1.173	PM8003 Option	has the meaning set forth in Section 2.1(a) (PM8003 Option);
1.174	PM8003 Option Exercise Date	has the meaning set forth in Section 2.1(a) (PM8003 Option);
1.175	PM8003 Option Exercise Notice	has the meaning set forth in Section 2.1(a) (PM8003 Option);
1.176	PM8003 Option Period	means the period from the [***] until [***] days after the Improved Licensed Product Conditions are met;
1.177	PM8003 Product-Specific Patent Right	means any Licensed Patent Right (including any Joint Patent Rights) that solely identifies or discloses or solely Covers a PM8003 Licensed Product(s) or its or their use or process of manufacture and does not claim or Cover any proprietary products Controlled by Biotheus other than such PM8003 Licensed Product(s). [***]
1.178	Preclinical Multispecific Licensed Compound	means [***];

1.179	Preclinical Multispecific Licensed Product	means, from and after the Preclinical Multispecific Option Exercise Date only, [***];
1.180	Preclinical Multispecific Option	has the meaning set forth in Section 2.1(b) (Preclinical Multispecific Option);
1.181	Preclinical Multispecific Option Exercise Date	has the meaning set forth in Section 2.1(b) (Preclinical Multispecific Option);
1.182	Preclinical Multispecific Option Exercise Notice	has the meaning set forth in Section 2.1(b) (Preclinical Multispecific Option);
1.183	Preclinical Multispecific Option Period	means, on a Preclinical Multispecific Licensed Compound-by Preclinical Multispecific Licensed Compound basis, the period from [***];
1.184	Preclinical Multispecific Product-Specific Patent Right	means, on a Preclinical Multispecific Licensed Product-by-Preclinical Multispecific Licensed Product basis, any Licensed Patent Right (including any Joint Patent Rights) that solely identifies or discloses or solely Covers a Preclinical Multispecific Licensed Product(s) or its or their use or process of manufacture and does not claim or Cover any proprietary products Controlled by Biotheus other than such Preclinical Multispecific Licensed Product(s). [***]
1.185	Pricing and Reimbursement Approval	means in any country where a Regulatory Authority authorizes, approves or determines reimbursement for or use of, and / or pricing for, pharmaceutical products, receipt (or, if required to make such authorization, approval or determination as effective, publication) of such reimbursement and / or pricing approval or determination (as the case may be);

1.186	Product-Specific IP	means, all Product-Specific Know-How and Product-Specific Patent Rights;
1.187	Product-Specific Know-How	means, for the purpose of Section 1.72 (Confidential Information) and Article 10 (Confidentiality), with respect to a Licensed Product any Licensed Know-How that solely relates to such Licensed Product;
1.188	Product-Specific Patent Right	means, on a Licensed Product-by-Licensed Product basis, any Licensed Patent Right (including any Joint Patent Rights) that solely identifies or discloses or solely Covers a Licensed Product(s) or its or their use or process of manufacture and does not claim or Cover any proprietary products Controlled by Biotheus other than such Licensed Product(s), including PM8002 Product-Specific Patent Right, PM8003 Product-Specific Patent Right and Preclinical Multispecific Product-Specific Patent Right;
1.189	Prohibited Conduct	has the meaning set forth in Section 11.3(c) (No Bribery);
1.190	Project Manager	has the meaning set forth in Section 4.3 (Alliance and Project Managers);
1.191	Proposed In-Licensed Rights	has the meaning set forth in Section 3.8 (New Biotheus In-Licenses);
1.192	Prosecution and Maintenance	has the meaning set forth in Section 9.2(d) (BioNTech-Prosecuted Patent Rights);
1.193	Qualification Date	has the meaning set forth in Article 8 (Financial Terms);
1.194	Receiving Party	has the meaning set forth in Section 10.1(a) (General);

- 1.195 **Registrational Clinical Trial** means a Clinical Trial of a product that is designed to, and for which the competent Regulatory Authority has provided guidance that the design of such Clinical Trial is sufficient to, ascertain efficacy and safety of such product in support of the preparation and submission of an MAA for such product to the competent Regulatory Authority, regardless of whether such trial is referred to as a Phase II Trial, Phase IIb Trial or Phase III Trial or otherwise. If a Clinical Trial of a product is not initially designed as a Registrational Clinical Trial but is later re-designed, converted or expanded into such a trial, then it shall be deemed to be a Registrational Clinical Trial as of the date of such re-design, conversion or expansion;
- 1.196 **Regulatory Authority** means, with respect to a country in the Territory, any national (e.g., the FDA), supra-national (e.g., the European Commission, the Council of the European Union, or the European Medicines Agency), regional, state or local regulatory authority, department, bureau, commission, council or other competent authority involved in the granting of any IND, Marketing Authorization, or other Regulatory Authorization including China's Human Genetic Resources Office, and China General Customs Administration;
- 1.197 **Regulatory Authorization** means all technical, medical and scientific licenses, registrations, authorizations and approvals (including approvals of INDs, MAAs, BLAs, variations, extensions, supplements and amendments, and labelling approvals and licences and permissions for the export of data and materials) of any Regulatory Authority, necessary or useful for the use, Development, Manufacture, and Commercialization of a pharmaceutical or biopharmaceutical product in a regulatory jurisdiction, including Pricing and Reimbursement Approvals;

1.198	Regulatory Documentation	means all applications, filings, registrations, licenses, authorizations and approvals, including all Regulatory Authorizations, all correspondence submitted to or received from Regulatory Authorities and all supporting documents relating to the Licensed Products and all data contained in any of the foregoing, including all IND, NDA, BLA, MAA, Pricing and Reimbursement Approvals, regulatory drug list, advertising and promotion documents, clinical data, adverse events files and complaint files;
1.199	[**]	[**]
1.200	Regulatory Filing	means, with respect to the Licensed Product, any submission to a Regulatory Authority of any appropriate regulatory application with respect to such Licensed Product, including any submission to a regulatory advisory board, MAA, and any variation, extension, supplement or amendment thereto. For the avoidance of doubt, Regulatory Filing shall include any IND, NDA, BLA, MAA or the corresponding applications in any other country or group of countries with respect to the Licensed Product;
1.201	Retained Territory	means China;
1.202	Royalties	has the meaning set forth in Section 8.5(a) (Royalty Rates for Licensed Products);
1.203	Royalty Rates	has the meaning set forth in Section 8.5(a) (Royalty Rates for Licensed Products);
1.204	Royalty Report	has the meaning set forth in Section 8.10 (Royalty Reports; Payments);
1.205	Royalty Term	means, [**] ;

1.206	Sales Milestone Event	has the meaning set forth in Section 8.4 (Sales Milestone Payments for Licensed Products);
1.207	Sales Milestone Payment	has the meaning set forth in Section 8.4 (Sales Milestone Payments for Licensed Products);
1.208	Single Agent Activity	means [***];
1.209	Sublicensee	means any Person, other than a Party or an Affiliate or Third Party Distributor of a Party, to whom a Party grants a sublicense of the licenses granted to such Party under this Agreement;
1.210	Target	means [***];
1.211	Tax or Taxation	means any form of tax or taxation, levy, duty, charge, social security charge, contribution or withholding of whatever nature (including any related fine, penalty, surcharge, or interest) imposed by, or payable to, a tax authority;
1.212	Technology Transfer Payment	has the meaning set forth in Section 8.2 (Technology Transfer Payment);
1.213	Term	has the meaning set forth in Section 13.1 (Term);
1.214	Terminated Products	has the meaning set forth in Section 13.3 (Effects of Termination);
1.215	Territory	means all countries of the world and all territories and possessions thereof excluding the Retained Territory;
1.216	Third Party	means any Person other than a Party or an Affiliate of a Party;
1.217	Third Party Distributor	means any Third Party, other than a Sublicensee, that distributes (but does not Develop or Manufacture) a Licensed Product directly to customers;

1.218	Third Party License	means a written agreement between a Party or its Affiliates and a Third Party to license or acquire Third Party Intellectual Property Rights for use in connection with the Development, Manufacture or Commercialization of a Licensed Product, but excluding any agreements with Third Party Distributors;
1.219	Third Party Upstream Licensor	has the meaning set forth in Section 8.10 (Royalty Reports; Payments);
1.22	Trademarks	means all registered and unregistered trademarks, service marks, trade dress, trade names, logos, insignias, symbols, designs, and all other indicia of ownership, and combinations thereof;
1.221	Trispecific Patent Right	means [***];
1.222	United States or U.S.	means the United States of America and all of its districts, territories and possessions;
1.223	Upfront Payment	has the meaning set forth in Section 8.1 (Upfront Payment);
1.224	Valid Claim	means [***];
1.225	VDR	means the virtual data room containing information, documents and data relating to the Licensed Compounds and Licensed Products made available by Biotheus to BioNTech prior to the Execution Date;
1.226	Withholding Party	has the meaning set forth in Section 8.17 (Withholding Taxes);

1.227 [***] means [***]; and

1.228 [***] means [***].

2 OPTIONS

2.1 Options to BioNTech

(a) PM8003 Option

As of the Effective Date Biotheus shall and shall procure that its Affiliates pause all clinical Development activities in relation to PM8003 Licensed Products until the expiry of the PM8003 Option Period. As of the Effective Date, Biotheus hereby grants to BioNTech the exclusive option, free of charge, exercisable at BioNTech's sole discretion during the PM8003 Option Period, to obtain the exclusive license set forth in Section 3.1(b) (PM8003 Licensed Products) with respect to PM8003 Licensed Products ("**PM8003 Option**"). BioNTech may exercise the PM8003 Option by delivering written notice of such exercise to Biotheus within the PM8003 Option Period ("**PM8003 Option Exercise Notice**"). [***] Upon BioNTech's delivery to Biotheus within the PM8003 Option Period of a PM8003 Option Exercise Notice the Parties shall determine whether filings are required under the HSR Act in connection therewith and, subject to the termination or expiration of any applicable waiting period or other applicable clearance under the HSR Act if any such filings are required ("**PM8003 Option Exercise Date**"), BioNTech will be granted the license set forth in Section 3.1(b) (PM8003 Licensed Products) with respect to the PM8003 Licensed Products. The exercise of the PM8003 Option shall not involve any upfront or option exercise payments being due to Biotheus and any milestones that have already been triggered by a Licensed Product(s) prior to the PM8003 Option Exercise Date shall not be due in respect of the PM8003 Licensed Product PROVIDED THAT any applicable milestones and royalties set forth in Article 8 (Financial Terms) will be reduced in accordance with the terms and conditions set forth in Section 8.7 (PM8003 Licensed Products). If the Parties determine that a filing is required under the HSR Act they will cooperate in good faith with the respect to the preparation and submission of such a filing as soon as reasonably possible and with respect to responding promptly to any questions raised in relation to such filing. BioNTech will be responsible for paying any

filing fees required to be paid in connection with such a filing. [***] After the PM8003 Option Exercise Date, BioNTech will be responsible for all Development, Manufacturing, regulatory activities for and Exploitation of PM8003 Licensed Products in the Territory and the costs and expenses in connection therewith and Biotheus will transfer to BioNTech the ownership of the IND for PM8003 Licensed Product for the Territory and any other Regulatory Filings for PM8003 Licensed Product for the Territory that are possessed or controlled by Biotheus or its Affiliates no more than [***] days following the PM8003 Option Exercise Date. At BioNTech's discretion, following the PM8003 Option Exercise Date and subject to Biotheus' then-current capacity, BioNTech may request that Biotheus continues certain activities in relation to PM8003 Licensed Product, [***] and in accordance with a PM8003 Licensed Product development plan as approved by the Parties in the JSC, following the PM8003 Option Exercise Date.

(b) **Preclinical Multispecific Option**

As of the Effective Date, Biotheus hereby grants to BioNTech the exclusive option, free of charge, exercisable at BioNTech's sole discretion during the Preclinical Multispecific Option Period, to obtain the exclusive license set forth in Section 3.1(c) (Preclinical Multispecific Licensed Products) with respect to Preclinical Multispecific Licensed Products ("**Preclinical Multispecific Option**"). BioNTech may exercise the Preclinical Multispecific Option by delivering written notice of such exercise to Biotheus within the Preclinical Multispecific Option Period ("**Preclinical Multispecific Option Exercise Notice**"). [***] Biotheus shall keep BioNTech regularly updated via the JSC of all Preclinical Multispecific Licensed Compounds and Preclinical Multispecific Licensed Products it is currently working on and provide updates on Development activities in respect of the same at each meeting of the JSC. The exercise of the Preclinical Multispecific Option shall not involve the payment to Biotheus of any upfront or option exercise payments and any milestones that have already been triggered by a Licensed Product(s) prior to the Preclinical Multispecific Option Exercise Date shall not be due in respect of Preclinical Multispecific Licensed Products, provided that any applicable milestones and royalties payable under Article 8 (Financial Terms) shall be reduced in accordance with the terms and conditions set forth in Section 8.8 (Preclinical Multispecific Licensed Products). Upon BioNTech's delivery to Biotheus within the Preclinical Multispecific Option Period of a Preclinical

Multispecific Option Exercise Notice the Parties shall determine whether filings are required under the HSR Act in connection therewith and, subject to the termination or expiration of any applicable waiting period or other applicable clearance under the HSR Act if any such filings are required ("**Preclinical Multispecific Option Exercise Date**"), BioNTech will be granted the license set forth in Section 3.1(c) (Preclinical Multispecific Licensed Products) with respect to the Preclinical Multispecific Licensed Products. If the Parties determine that a filing is required under the HSR Act they will cooperate in good faith with the respect to the preparation and submission of such a filing as soon as reasonably possible and with respect to responding promptly to any questions raised in relation to such filing. BioNTech will be responsible for paying any filing fees required to be paid in connection with such a filing. Promptly and in any event within [***] days of the Preclinical Multispecific Option Exercise Date, Biotheus will at its cost and expense, provide BioNTech with the equivalent of the information set out in Section 3.4(a) (Knowledge and Technology Transfer) in respect of each such Preclinical Multispecific Licensed Product. After the Preclinical Multispecific Option Exercise Date, BioNTech will be responsible for all Development, Manufacturing, regulatory activities for and Exploitation of Preclinical Multispecific Licensed Products in the Territory and the costs and expenses in connection therewith. At BioNTech's discretion, following the Preclinical Multispecific Option Exercise and subject to Biotheus' then-current capacity, BioNTech may request that Biotheus continues certain activities in relation to Preclinical Multispecific Licensed Compound, [***] and in accordance with a Preclinical Multispecific Licensed Product development plan as approved by the Parties in the JSC, following the Preclinical Multispecific Option Exercise Date.

(c) **Biotheus Obligations**

During the PM8003 Option Period and Preclinical Multispecific Option Period (as the case may be) Biotheus shall not and shall procure that its Affiliates shall not enter into or discuss entering into any agreement or other arrangement with any Third Party pursuant to which such Third Party is granted rights or an option to obtain rights in relation to the PM8003 Licensed Compound or PM8003 Licensed Product or Preclinical Multispecific Licensed Compound or Preclinical Multispecific Licensed Product, as the case may be.

(d) **Option Exercise**

- (i) If BioNTech does not exercise the PM8003 Option during the PM8003 Option Period then BioNTech will not receive the license set forth in Section 3.1(b) (PM8003 Licensed Products), BioNTech will have no further rights or obligations with respect to PM8003 Licensed Compounds or PM8003 Licensed Products, PROVIDED THAT Biotheus may not resume Development and other Exploitation of PM8003 Licensed Compounds and PM8003 Licensed Products until the expiry of the PM8003 Option Period;
- (ii) If BioNTech does not exercise the Preclinical Multispecific Option during the Preclinical Multispecific Option Period, then BioNTech will not receive the license set forth in Section 3.1(c) (Preclinical Multispecific Licensed Products), BioNTech will have no further rights or obligations with respect to such Preclinical Multispecific Licensed Compounds or Preclinical Multispecific Licensed Products, PROVIDED THAT Biotheus may not resume Development and other Exploitation of such Preclinical Multispecific Licensed Compounds and Preclinical Multispecific Licensed Products until the First Commercial Sale of a Licensed Product pursuant to this Agreement by or on behalf of BioNTech, its Affiliate or Sublicensee.

2.2 **Option to Biotheus**

[***]

3 **LICENSES; EXCLUSIVITY**

3.1 **License Grants to BioNTech.** Subject to terms and conditions of this Agreement,

(a) **PM8002 Licensed Products**

Effective as of the Effective Date, Biotheus hereby grants BioNTech an exclusive, royalty-bearing, sublicensable through multiple tiers (in accordance with Section 3.2 (Sublicensing Rights)) license under the Licensed IP to Exploit PM8002 Licensed Products in the Field in the Territory.

(b) **PM8003 Licensed Products**

Effective as of the PM8003 Option Exercise Date, Biotheus hereby grants BioNTech an exclusive, royalty-bearing, sublicensable through multiple tiers (in accordance with Section 3.2 (Sublicensing Rights)) license under the Licensed IP to Exploit PM8003 Licensed Products in the Field in the Territory.

(c) **Preclinical Multispecific Licensed Products**

Effective as of the Preclinical Multispecific Option Exercise Date with respect to a Preclinical Multispecific Licensed Product and on a Preclinical Multispecific Licensed Product -by -Preclinical Multispecific Licensed Product basis, Biotheus hereby grants BioNTech an exclusive, royalty-bearing, sublicensable through multiple tiers (in accordance with Section 3.2 (Sublicensing Rights)) license under the Licensed IP to Exploit any applicable Preclinical Multispecific Licensed Product in the Field in the Territory.

(d) **Product License Exclusivity**

The licenses granted in Sections 3.1(a) (PM8002 Licensed Products), 3.1(b) (PM8003 Licensed Products) and 3.1(c) (Preclinical Multispecific Licensed Products) shall be exclusive in the Territory, even as to Biotheus, except as required for Biotheus to perform its obligations under the Global CDP and Joint CDP in accordance with the terms of this Agreement.

(e) **Retained Rights in the Retained Territory**

(i) Following the Effective Date and during the Term:

- (A) Biotheus may not license, assign, transfer or grant any rights relating to the Licensed Compounds or Licensed Products in the Retained Territory to a BioNTech Retained Territory Competitor; and
- (B) Biotheus shall ensure that any transfer, licence or other grant of rights relating to the Licensed Compounds or Licensed Products in the

Retained Territory to a Third Party that is not a BioNTech Retained Territory Competitor shall be subject to the rights granted to BioNTech pursuant to this Agreement. Biotheus will ensure that any such transfer, licence or other grant of rights: (1) is consistent with the terms of this Agreement, and (2) requires the relevant transferee, licensee or other assignee or partner to comply with Biotheus' relevant obligations under this Agreement, including in relation to intellectual property, confidentiality and publications. Biotheus will remain responsible and liable for the performance of all its transferees, licensees and other assignees or partners under their respective licensed, assigned or transferred or partnered rights to the same extent as if such activities were conducted by Biotheus. Biotheus will deliver to BioNTech prompt written notice of any license or other partnering, assignment or transfer agreement relating to the Licensed Products in the Retained Territory with a Third Party no later than [***] days following the execution thereof and shall provide BioNTech with a copy of each such license or other agreement (and any amendment thereto) within [***] days after execution thereof (which copy may be redacted of any confidential or proprietary information that is not necessary for BioNTech to confirm or verify Biotheus' compliance with this Agreement). Subject to Section 3.1(e)(i) (Retained Rights in the Retained Territory), Biotheus retains the right to Exploit Licensed Products in the Field in the Retained Territory, except as required for BioNTech to (i) perform its obligations under the Global CDP and Joint CDP in accordance with the terms of this Agreement and (ii) exercise its rights pursuant to Section 3.1(f) (Manufacture in the Retained Territory).

- (C) For clarity, subject to Section 3.3 (Subcontractors) and Section 4.5(b) (Escalation) the provisions of Sections 3.1(e)(i)(A) and 3.1(e)(i)(B) above shall not prevent Biotheus [***] to conduct any activities with respect to the Exploitation of the Licensed Products in the Retained Territory and the restrictions in Section 3.1(e)(i)(A) and the reporting requirements in Section 3.1(e)(i)(B) shall not apply to [***].

(f) **Manufacture in the Retained Territory**

Effective as of the Effective Date in respect of PM8002 Licensed Compounds, as of the PM8003 Option Exercise Date in respect of PM8003 Licensed Compounds, and as of the Preclinical Multispecific Option Exercise Date in respect of Preclinical Multispecific Licensed Products, Biotheus hereby grants BioNTech a co-exclusive royalty-free, sublicensable through multiple tiers (in accordance with Section 3.2 (Sublicensing Rights)) license under the Licensed IP (and any equivalent Patent Rights and Know-How Controlled by Biotheus and its Affiliates in the Retained Territory) to Manufacture the Licensed Compounds and Licensed Products in the Retained Territory; PROVIDED THAT: (i) such Manufacture is solely for the purpose of Developing and Commercialising the Licensed Compounds and Licensed Products in the Field in the Territory; and [***] and acting reasonably and in good faith, subject to Biotheus demonstrating it has sufficient then-current capacity and capability, and the Parties shall for a period of [***] days thereafter discuss [***] terms for a manufacture and supply agreement under which Biotheus will manufacture and supply BioNTech's requirements for such Licensed Compounds and/or Licensed Products in the Retained Territory. For clarity, if the Parties do not agree the terms of such manufacture and supply agreement within [***] days then BioNTech will be free to use a Third Party to Manufacture such Licensed Compounds and Licensed Products in the Retained Territory, [***]. [***].

3.2 **Sublicensing Rights**

(a) **Sublicenses**

Subject to the terms of this Agreement, including Section 3.2(b) (Sublicense Requirements), BioNTech may grant sublicenses of any rights granted by Biotheus under Section 3.1 (License Grants to BioNTech) through multiple tiers to any of its Affiliates or to one or more Sublicensees.

(b) **Sublicense Requirements**

BioNTech will ensure that all permitted sublicenses granted under this Agreement: (a) are consistent with the terms of this Agreement, and (b) require the Sublicensee to comply with BioNTech's obligations under this Agreement, including the confidentiality and non-use obligations set forth in Section 10.1 (Confidentiality). BioNTech will remain responsible and liable for the performance of all Affiliates and Sublicensees under their respective sublicensed rights to the same extent as if such activities were conducted by BioNTech. [***]. If BioNTech or any of its Affiliates grants a sublicense to any Sublicensee under the rights granted hereunder in relation to the Licensed Compounds, [***].

3.3 **Subcontractors**

Each Party may perform any of its obligations or exercise its rights under this Agreement through one or more subcontractors; provided that (a) the subcontracting Party will not engage any subcontractor that has been debarred by any Regulatory Authority; (b) the subcontracting Party remains fully responsible for the work allocated to, and payment to, such subcontractors to the same extent it would if it had done such work itself; (c) the subcontractor undertakes in writing obligations of confidentiality and non-use applicable to the Confidential Information that are at least as stringent as those set forth in Section 10.1 (Confidentiality); (d) in the case of Biotheus any such subcontractor appointed by Biotheus in connection with performing services for Biotheus under the Global CDP or the Joint CDP under this Agreement in the Retained Territory or the Manufacturing activities contemplated to be conducted by Biotheus under Article 7 (Manufacturing and Technology Transfer) has been both successfully qualified and prior approved by BioNTech in writing (unless otherwise agreed by the Parties in writing); (e) the subcontractor agrees in writing to assign or grant a sublicensable license to the subcontracting Party to all Know-How and Patent Rights developed or invented by the subcontractor in performing services for the Party under this Agreement that are necessary or useful for the Development, Manufacture or Commercialization of any Licensed Product; and (f) the subcontracting Party will be liable for any act or omission of any subcontractor that is a breach of any of the subcontracting Party's obligations under this Agreement as though the same were a breach by the subcontracting

Party, and the non-subcontracting Party will have the right to proceed directly against the subcontracting Party without any obligation to first proceed against such subcontractor.

3.4 Knowledge and Technology Transfer

- (a) Within [***] days of the Effective Date, (1) Biotheus will deliver to BioNTech and cause its Affiliates to deliver: (i) [***] copies of the VDR with the content as it existed at the Execution Date; and (ii) any information, documents or data in the possession or control of Biotheus or its Affiliates relating to the Licensed Compounds and Licensed Products that are not included in the VDR and (2) Biotheus will share such information [***] as agreed between the Parties.
- (b) Throughout the Term, Biotheus will to BioNTech, and cause its Affiliates to deliver, copies of (a) the written Licensed Know-How related to each Licensed Product, (b) documents and files related to the Licensed Patent Rights related to each Licensed Product, and (c) any other Licensed Know-How that is necessary or useful for the Exploitation of any Licensed Product in accordance with this Agreement; PROVIDED THAT any Licensed Know-How relating to Manufacturing will be disclosed to BioNTech in accordance with Article 7 (Manufacturing and Technology Transfer).
- (c) As part of any Know-How transfer in accordance with Section 3.4(a) (Knowledge and Technology Transfer), and as otherwise required by the Global CDP and Joint CDP, (a) Biotheus will transfer to BioNTech Biotheus Materials, and (b) BioNTech will transfer to Biotheus BioNTech Materials, in each case related to any Licensed Product to the extent necessary or useful for the Parties to perform their respective obligations, and in the case of BioNTech to exercise the rights granted to it, under this Agreement. Any Materials provided by a Party in accordance with this Section 3.4(c) (Knowledge and Technology Transfer) will remain the sole property of the supplying Party.
- (d) Biotheus will be responsible for all costs and expenses associated with the transfer to BioNTech of documentation and Materials and any Licensed Know-How in accordance with Sections 3.4(a) to 3.4(c) (Knowledge and Technology Transfer). Unless otherwise agreed by the Parties in writing, Biotheus will make appropriate

personnel who are fluent in English available to BioNTech at reasonable times and upon reasonable prior notice at no cost for the purpose of assisting BioNTech in understanding and using the Licensed Know-How in accordance with this Agreement.

3.5 **No Implied Licenses; Retained Rights**

Each Party acknowledges that the rights and licenses granted under this Agreement are limited to the scope expressly granted herein, and Biotheus expressly reserves the rights under the Licensed IP to exercise its rights in the Retained Territory and perform its obligations under the Global CDP and Joint CDP. Except for the rights expressly granted under this Agreement, no rights, title, licenses, or other interests of any nature whatsoever are granted whether by implication, estoppel, reliance, or otherwise, by either Party to the other Party. Accordingly, BioNTech will not practice or Exploit the Licensed Know-How and Licensed Patent Rights other than as expressly licensed in this Agreement, and Biotheus will not practice or Exploit the BioNTech Background IP or the BioNTech Foreground IP other than as expressly licensed in this Agreement. For clarity, (a) the licenses granted by Biotheus to BioNTech under this Agreement shall not include any license to Exploit any Biotheus proprietary component or product in combination with a Licensed Product; and (b) Biotheus shall not be entitled to Exploit the Licensed Products in the Retained Territory in combination with any BioNTech proprietary product or In-Licensed BioNTech Product without BioNTech's prior consent, which shall not be unreasonably withheld or conditioned.

3.6 **Biotheus Exclusivity**

(a) **Biotheus Exclusivity**

During the period from the Effective Date until the First Commercial Sale of a Licensed Product, except for the Exploitation of Licensed Products in the Retained Territory, Biotheus shall not (and shall procure that its Affiliates do not) either on its own or with a Third Party (i) research, Develop, Manufacture or Commercialize [***]; or (ii) clinically Develop, Manufacture or Commercialize any [***]. For clarity, the foregoing shall not restrict Biotheus from Developing or otherwise Exploiting any products containing [***].

(b) [***]

[***]

(c) **BioNTech Competitor**

If a BioNTech Competitor becomes an Affiliate of Biotheus after the Execution Date (i) such Affiliate shall not have any access to any BioNTech Background IP or BioNTech Foreground IP or any Confidential Information of BioNTech; and (ii) Biotheus and such Affiliate shall institute commercially reasonable technical and administrative procedures and safeguards designed to ensure that the requirements set forth in the foregoing Section 3.6(c)(i) are met, including by creating "firewalls" between (X) the personnel working on any activities of such Affiliate and (Y) the personnel working on activities under this Agreement.

3.7 **BioNTech Exclusivity and Improved Licensed Product Conditions**

[***]

3.8 **New Biotheus In-Licenses**

If Biotheus or any of its Affiliates intends to become a party to a license, sublicense or other agreement for additional rights that are necessary or reasonably useful for the Exploitation of any Licensed Product in the Field in the Territory, then Biotheus shall provide BioNTech with the proposed details of the applicable rights and Biotheus' proposal for the terms of the applicable agreement in advance ("**Proposed In-Licensed Rights**"). Where such Proposed In-Licensed Rights are necessary for the Exploitation of any Licensed Product in the Field in the Territory, (a) BioNTech shall have the first right to negotiate and execute such license PROVIDED THAT in relation to (i) PM8003 Licensed Products prior to the PM8003 Option Exercise Date or (ii) Preclinical Multispecific Licensed Products prior to the Preclinical Multispecific Option Exercise Date, the Parties shall mutually agree on whether to negotiate such a license and which Party should take the lead in such negotiations; and (b) if BioNTech does not negotiate and execute such license, Biotheus shall obtain BioNTech's prior written consent to such Proposed In-Licensed Rights in advance in writing and shall consult and take

account of BioNTech's comments in the negotiation of any agreement relating to such Proposed In-Licensed Rights. In the case of the foregoing (b), Biotheus shall ensure that Proposed In-Licensed Rights are sublicensable to BioNTech pursuant to this Agreement. Promptly following execution of any agreement relating to any Proposed In-Licensed Rights, Biotheus shall provide BioNTech with such agreement, subject to customary and reasonable redaction. If BioNTech notifies Biotheus in writing that it wishes to take a sublicense under Proposed In-Licensed Rights pursuant to this Agreement, then (1) the Proposed In-Licensed Rights shall automatically be included in the Licensed IP hereunder; and (2) such license, sublicense or other agreement shall be a "Biotheus In-License" hereunder. Otherwise, notwithstanding anything to the contrary in this Agreement, the Proposed In-Licensed Rights will not be included within the Licensed IP and such license, sublicense or other agreement shall not be a "Biotheus In-License" hereunder.

3.9 [***]

[***]

4 GOVERNANCE.

4.1 Joint Steering Committee

(a) Formation and Purpose of the JSC

Promptly, but no later than [***] days after the Effective Date, the Parties will establish a Joint Steering Committee (" JSC"), which JSC will coordinate and oversee the Parties' activities hereunder in accordance with this Section 4.1 (Joint Steering Committee). The JSC will have the responsibilities set forth herein and will continue in operation for the Term unless dissolved earlier by the mutual agreement of the Parties.. Notwithstanding the foregoing, [***] may at its option and by prior written notice to [***] determine that the JSC under this Agreement (and any applicable Subcommittees) [***].

(b) **Membership**

Each Party will designate [***] representatives with appropriate expertise and seniority to serve as members of the JSC, and who have the authority to bind such Party with respect to matters within the purview of the JSC. Each Party may replace its JSC representatives at any time upon written notice to the other Party. [***] will designate [***] of its JSC members as the chairperson of the JSC. The Parties, through the Alliance Managers, will alternate in calling meetings and preparing and circulating an agenda in advance of each meeting. The Party that was not responsible for preparing the meeting agenda will prepare and circulate for review and approval by the other Party written minutes of such meeting within [***] days after such meeting. The Parties will agree on the minutes of each meeting promptly, but in no event later than [***] Business Days after receipt of such minutes.

(c) **Meetings**

It is the intention of the Parties that the JSC will hold meetings [***], save that each Party may request and convene a JSC meeting and propose agenda therefor at any time. The JSC will meet virtually save that the JSC will have the option of meeting in person once per year alternately at a location agreed by the Parties. The Alliance Manager of each Party or his or her designee will attend each meeting of the JSC as a non-voting participant. Each Party will be responsible for all of its own expenses of participating in any JSC meeting.

(d) **Meeting Agendas**

Each Party will disclose to the other Party the proposed agenda items along with appropriate information at least [***] Business Days in advance of each meeting of the JSC. Notwithstanding the foregoing, under exigent circumstances requiring JSC input, a Party may provide its agenda items to the other Party within a lesser period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, so long as such other Party consents to such later addition of such agenda items or the absence of a specific agenda for such JSC meeting.

(e) **Specific Responsibilities of the JSC**

The responsibilities of the JSC will be to:

- (i) oversee the overall strategic relationship between the Parties and the Development, Manufacturing and Commercialization of Licensed Products in the Territory and the Retained Territory;
- (ii) review and discuss the Development of Licensed Products pursuant to the Global CDP and Joint CDP;
- (iii) review, discuss and approve the Global CDP and Joint CDP and any updates thereto;
- (iv) provide a forum to discuss and coordinate the Parties' respective activities in the Territory and the Retained Territory in respect of Licensed Products (including but not limited to the adoption of and amendments to clinical development plans and clinical protocols specific to the Territory or the Retained Territory); and
- (v) perform such other functions as appropriate to further the purposes of this Agreement as determined by the Parties.

4.2 **Subcommittees**

(a) **General**

The JSC will be entitled to form subcommittees or working groups to which it may delegate responsibilities to carry out certain activities allocated by the JSC; any such subcommittees will be governed by the rules established by the JSC and may make such decisions in lieu of the JSC as delegated by the JSC. Any disputes arising from such a subcommittee shall be escalated to the JSC for resolution.

(b) **Joint Development and Operations Working Group**

Without limiting Section 4.2(a) (Subcommittees):

- (i) Promptly after the Effective Date, the JSC shall establish a joint development and operations working group (the “ **Joint Development and Operations Working Group**”) chaired by BioNTech comprised of an equal number of representatives from each Party. The Joint Development and Operations Working Group shall act as a forum for the Parties to (A) discuss and align on Development activities in their respective territories; (B) oversee the implementation and progress of the Global CDP and the Joint CDP; (C) to discuss and propose to the JSC for approval any amendments to the Global CDP or Joint CDP; and (D) oversee any Global Trials. The Joint Development and Operations Working Group will continue in operation for the Term unless dissolved earlier by the mutual agreement of the Parties.
- (ii) The JSC shall determine the desired membership of the Joint Development and Operations Working Group and once formed, the Parties shall mutually determine the time, place and procedure of meetings. The Parties, through their designated lead individuals, will alternate in calling meetings and preparing and circulating an agenda in advance of each meeting of the Joint Development and Operation Working Group. [***]

(c) **Joint IP Committee**

Without limiting Section 4.2(a) (Subcommittees):

- (i) No later than [***] days after the Effective Date, the JSC shall establish a joint intellectual property committee (the “ **Joint IP Committee**”) chaired by BioNTech and comprised of an equal number of representatives from each Party. The Joint IP Committee shall act as a forum for the Parties to discuss and align on patenting strategies with regard to Licensed Products and coordinate the Parties' efforts in accordance with the provisions of Article 9 (Intellectual Property) and other matters related to the prosecution and maintenance of Intellectual Property Rights hereunder, including submissions to and addressing notices from Regulatory Authorities that

relate to regulatory-patent linkage procedures and proceedings. The Joint IP Committee will continue in operation for the Term unless dissolved earlier by the mutual agreement of the Parties.

- (ii) The JSC shall determine the desired membership of the Joint IP Committee and once formed, the Parties, through their designated IP leads, shall determine the time, frequency, place and procedure of meetings. The Parties, through their designated IP leads, will alternate in calling meetings and preparing and circulating an agenda in advance of each meeting of the Joint IP Committee and will also alternate in preparing and circulating meeting minutes of each meeting of the Joint IP Committee. [***]

4.3 Alliance and Project Managers

Each of the Parties will appoint a project manager (the "**Project Manager**") who shall be responsible for implementing and coordinating activities and facilitating the exchange of information between the Parties. Each of the Parties will also appoint a single individual to ensure clear and responsive communication between the Parties and the effective exchange of information (each, an "**Alliance Manager**"). The role of the Alliance Manager is to act as a single point of contact between the Parties to ensure a successful relationship under this Agreement. The Alliance Managers will attend any JSC meetings. Alliance Managers will be non-voting participants in all JSC meetings that they attend; *provided, however*, that an Alliance Manager may bring any matter to the attention of the JSC if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party will designate its initial Alliance Manager promptly after the Effective Date and each Party may change its designated Alliance Manager at any time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party. Each Alliance Manager will also: (a) be the point of first referral in all matters of conflict resolution; and (b) identify and bring disputes to the attention of the JSC in a timely manner.

4.4 Additional Participants

With the consent of the other Party, not to be unreasonably withheld, conditioned, or delayed, other employees of either Party or any of its Affiliates involved in the Development, Manufacturing or Commercialization of any Licensed Products may attend meetings of the JSC as non-voting participants. In addition, with the consent of each Party, consultants, representatives, or advisors involved in the Development, Manufacturing or Commercialization of any Licensed Products may attend meetings of the JSC as non-voting observers; *provided, however*, that such Third Party participants and observers are under written obligations of confidentiality and non-use applicable to the Confidential Information of each Party that are at least as stringent as those set forth in Section 10.1 (Confidentiality).

4.5 Decision-Making

(a) Committee Decisions

Each Party's representatives on the JSC will^{***} on all matters brought before such committee for a decision by consensus. The JSC will make decisions as to matters within its jurisdiction by unanimous vote, which vote may either be reflected in the minutes of the committee meeting or by written consent signed by the chairperson or his or her designee identified in writing. No vote will be binding on either Party unless each Party has ^{***} members of JSC as representatives in attendance.

(b) Escalation

In the event the JSC is unable to reach a decision by unanimous consensus, at the election of either Party, such Party may refer any other matters requiring the approval of the JSC to the Party's Executive Officer. The Executive Officers will use good faith efforts to resolve any such disagreement so referred to them as soon as practicable, and any final decision that the Executive Officers agree to in writing will be conclusive and binding on the Parties. If the Executive Officers are unable to resolve any disagreement so referred within a period of ^{***} days after such matter is referred to them (or such longer period as the Executive Officers may agree upon), then (i) BioNTech will have final decision-making authority with respect to the final resolution

of any disagreement requiring the approval of the JSC regarding activities in the Territory, all Global Trials, the Global CDP, the Joint CDP; [***] (ii) subject to Section 4.5(b)(i) above, Biotheus will have final decision-making authority with respect to the final resolution of any disagreement requiring the approval of the JSC regarding activities in the Retained Territory; and (iii) each Party will have final say in relation to the matters which such Party has final control over in Article 9 (Intellectual Property); PROVIDED THAT (A) both Biotheus and BioNTech shall conduct all Development and other Exploitation of the Licensed Products in the Retained Territory in accordance with the Global CDP and the Global Commercialization Strategy; [***].

4.6 General Authority

The JSC and Alliance Manager will have solely the powers expressly assigned to them in this Article 4 (Governance) and elsewhere in this Agreement. In conducting themselves on the JSC and as Alliance Managers, and in exercising their rights under this Article 4 (Governance), all representatives of each Party will consider diligently, reasonably and in good faith all input received from the other Party, and will use good faith efforts to reach unanimity, where required, on all matters before them. Notwithstanding anything to the contrary set forth in this Agreement, the JSC will not have the right to make any decisions:

- (a) to amend or modify this Agreement, or waive compliance with this Agreement;
- (b) in a manner that excuses such Party from any obligation specifically enumerated under this Agreement;
- (c) in a manner that negates any consent right or other right specifically allocated to the other Party under this Agreement;
- (d) to resolve any dispute involving the breach or alleged breach of this Agreement;
- (e) to resolve a matter if the provisions of this Agreement specify that agreement of the Parties, including consent of each Party, is required for such matter;
- (f) in a manner that the other Party reasonably believes would require such other Party to perform any act that would cause such Party to violate any Applicable Law or the

requirements of any Regulatory Authority, or otherwise breach any of its obligations hereunder; or

- (g) otherwise expand the rights or reduce the obligations of either Party under this Agreement.

5 DEVELOPMENT AND COMMERCIALIZATION

5.1 Responsibilities

(a) Global Commercialization Strategy

BioNTech shall prepare and have final say with regard to (including all updates thereto) a global commercialization strategy relating to the Commercialization of Licensed Products on a worldwide basis on the overall global branding (which is only applicable if the Parties agree to global branding), marketing, communication, positioning and medical strategies for Licensed Products, a description of any global level programs to be conducted and pricing guidelines and policy with respect to the Licensed Products ("**Global Commercialization Strategy**"). [***] BioNTech shall provide Biotheus with its draft Global Commercialization Strategy and any draft amendments thereto sufficiently in advance of the proposed adoption to afford Biotheus a reasonable opportunity to review and comment on the drafts and shall consider Biotheus' comments and suggestions in good faith and shall incorporate any local requirements required by Applicable Law for the Retained Territory. Each Party will comply with the Global Commercialization Strategy in Commercializing Licensed Products in the Territory or the Retained Territory, as applicable. Notwithstanding the foregoing, Biotheus shall not be bound by any provisions in the Global Commercialization Strategy (as may be amended and supplemented) that are related to [***] of the Licensed Products in the Retained Territory.

(b) Formation of Joint Commercialization Working Group

The Parties will form a joint commercialization working group ("**JCWG**"). The working group will provide a forum for the Parties to coordinate Commercialization activities in

relation to Licensed Products as between the Territory and the Retained Territory, for BioNTech to provide any updates to Biotheus with regards to the Global Commercialization Strategy, and for Biotheus to provide any updates to BioNTech on its Commercialization activities in the Retained Territory to as to demonstrate consistency with the Global Commercialization Strategy. The JCWG will consist of an equal number of representatives from each Party having experience in the Commercialization of pharmaceutical products. The JCWG will meet [***] or at such other frequency as the JCWG shall agree.

(c) **Responsibilities in the Territory**

Subject to the terms of this Agreement, BioNTech, either on its own or through Affiliates or Third Parties, shall have sole discretion over, and the sole right and responsibility for, at its sole cost and expense, the Development, Manufacture and Commercialization of Licensed Products in the Territory. Subject to Section 4.5 (Decision-Making), as between BioNTech and Biotheus, BioNTech shall have the sole decision-making authority for the operations, Development, Manufacture and Commercialization strategies and decisions, including funding and resourcing, related to the Development, Manufacture and Commercialization of Licensed Products in the Territory.

(d) **Responsibilities in the Retained Territory**

Subject to the terms of this Agreement, Biotheus, either on its own or through Affiliates or Third Parties, shall have sole discretion over, and the sole right and responsibility for, at its sole cost and expense, the Development, Manufacture and Commercialization of Licensed Products in the Retained Territory. Subject to Section 4.5 (Decision-Making), as between BioNTech and Biotheus, Biotheus shall have the sole decision-making authority for the operations, Development, Manufacture and Commercialization strategies and decisions, including funding and resourcing, related to the Development, Manufacture and Commercialization of Licensed Products in the Retained Territory.

5.2 **Diligence Obligation**

BioNTech shall use Commercially Reasonable Efforts to [***].

5.3 **Clinical Development Plans**

(a) **Global CDP**

The Parties will agree in the JSC on a detailed clinical development plan (including any preclinical studies required to support clinical development activities) for any globally conducted trials for Licensed Products that recruit patients from both the Territory and the Retained Territory (the “**Global Trials**”), including a budget for development and manufacturing costs (the “**Global CDP**”). BioNTech shall propose the draft of Global CDP to the JSC within [***] Business Days after the Effective Date and the Global CDP will be amended with new data/information as appropriate; [***]. An outline of the Global CDP is set out in Schedule 1. Pursuant to the Global CDP, [***] will be responsible for recruiting from the Retained Territory [***] of the total number of patients proposed for the applicable Global Trial, PROVIDED THAT such percentage may be adjusted by agreement of the Parties if required by a relevant Regulatory Authority. Any Global Trial will be run by or on behalf of BioNTech and BioNTech will be the regulatory sponsor of any Global Trial. Each Party will bear the costs associated with the conduct of any Global Trial in its respective territory, meaning that [***] shall bear the costs of recruiting from the Retained Territory [***] of the total number of patients for a Global Trial as set out in this Section 5.3(a) (Global CDP) (or, if applicable, any adjusted percentage agreed between the Parties if required by a relevant Regulatory Authority). [***] For clarity, Biotheus shall not be obligated to bear any costs or expenses of any Global Trials save as expressly contemplated by this Section 5.3(a) (Global CDP) (unless otherwise agreed between the Parties).

(b) **Joint CDP**

Subject to Biotheus' then-current capacity, the Parties will agree in the JSC on a detailed clinical development plan for any trials for Licensed Products to be conducted

by Biotheus on BioNTech's behalf at BioNTech's cost that recruit patients from the Territory (the " **Joint Trials**"), including a budget for development and manufacturing costs (the " **Joint CDP**"). Such Joint CDP will be agreed between the Parties within two [***] after the Effective Date and will be amended from time to time. An outline of the [***]. The Joint CDP will include: (a) the principal Development objectives to be undertaken, (b) the specific activities to be performed by Biotheus and any activities to be performed by BioNTech, and (c) the estimated timelines and a budget for expected Internal Costs and estimated External Expenses for the performance of such activities by Biotheus. Biotheus will provide BioNTech with updates on material developments (including preclinical and clinical Development activities), findings and issues as soon as they arise in respect of activities undertaken by Biotheus pursuant to the Joint CDP in addition to regular updates in writing at least [***] on activities completed and progress made under such plan. Biotheus shall also provide with each update to BioNTech all data and results generated in carrying out the activities under the Joint CDP since the last update and shall make available Biotheus personnel to discuss such data and results. Any Joint Trial will be run by Biotheus on behalf of BioNTech and BioNTech will be the regulatory sponsor of any Joint Trial. The costs of such Joint Trials will be borne by BioNTech in accordance with Section 5.3(d) (Eligible Development Costs for the Joint CDP).

(c) **Changes to Global CDP and Joint CDP**

The JSC shall review the Global CDP and the Joint CDP as appropriate and shall update the plan accordingly. Either Party may suggest to the JSC modifications to the Global CDP and the Joint CDP which modifications will be reviewed and agreed by the JSC. If the JSC cannot reach consensus with respect to changes to the Global CDP and the Joint CDP within [***] days of updates thereto being proposed to the JSC, subject to the restriction set forth in Sections 4.5(b) (Escalation) and 5.3(a) (Global CDP), BioNTech shall have final say with regard to setting the content of such Global CDP and the Joint CDP.

(d) **Eligible Development Costs for the Joint CDP**

Subject to the provisions of Section 7.1(b) (Supplies of PM8002 Licensed Products for Global CDP and Joint CDP), BioNTech will be responsible for the Eligible Development Costs incurred by Biotheus in the performance of Joint CDP Activities allocated to Biotheus under the Joint CDP, unless agreed otherwise by the Parties. BioNTech shall reimburse Biotheus for such Eligible Development Costs incurred in accordance with the budget set out in the Joint CDP by quarterly payments in arrears. BioNTech shall have no obligation to reimburse Biotheus for Eligible Development Costs incurred by Biotheus that are not included in the budget set out in the Joint CDP. Biotheus shall submit invoices for Eligible Development Costs to BioNTech at [***] and BioNTech shall make payment for Eligible Development Costs within [***] days following the receipt of an undisputed invoice from Biotheus. Each such invoice shall be accompanied by reasonable supporting documentation with respect to the Eligible Development Costs included in such invoice.

(e) **Eligible Development Costs for the Global CDP**

Subject to the provisions of Section 7.1(b) (Supplies of PM8002 Licensed Products for Global CDP and Joint CDP), each Party will bear the Eligible Development Costs incurred in carrying out the Global CDP Activities in its respective territory, which in the case of Biotheus shall include the costs of recruiting patients from the Retained Territory for a Global Trial as set out in Section 5.3(a) (Global CDP).

(f) **BioNTech Right to Carry out Activities**

BioNTech shall have the right but not the obligation to carry out any Joint CDP Activities or Global CDP Activities that are allocated to Biotheus if Biotheus fails to carry out such Joint CDP Activities or Global CDP Activities in accordance with the Joint CDP or Global CDP and the terms of this Agreement. In such circumstances BioNTech shall have no obligation to reimburse Biotheus for the Eligible Development Costs incurred by Biotheus for the activities which Biotheus failed to carry out in accordance with the Joint CDP or Global CDP and the terms of this Agreement.

5.4 Conduct of Global CDP and Joint CDP Activities

- (a) Following the Effective Date, BioNTech will take over as regulatory sponsor with respect to any Clinical Trials with respect to Licensed Products ongoing as at the Effective Date in the Territory. The Parties will discuss and agree the timing and process for such transfer via the JSC.
- (b) Each Party will ensure that it allocates the appropriate number of suitably qualified staff to carry out the Global CDP Activities and Joint CDP Activities. All communications in respect of the Global CDP Activities and Joint CDP Activities will be carried out in English.
- (c) Each Party will execute (itself or through its Affiliates or any subcontractor) the Global CDP Activities and Joint CDP Activities allocated to it set forth therein in accordance with the Global CDP and Joint CDP to achieve the objectives in the Global CDP and Joint CDP as applicable.
- (d) Each Party: (a) will comply with all Applicable Laws in the performance of work under this Agreement and the Global CDP and Joint CDP and shall ensure that its Affiliates and subcontractors (as applicable) execute any Global CDP Activities and Joint CDP Activities on such Party's behalf under this Agreement and the Global CDP and Joint CDP in compliance with all Applicable Laws, and (b) shall, and shall procure that its Affiliates and subcontractors (as applicable), undertake the Global CDP Activities and Joint CDP Activities in good scientific manner and using appropriately skilled personnel. Without limiting the foregoing or any other provision of this Agreement, if a relevant Regulatory Authority finds (via an inspection or otherwise) that Biotheus, its Affiliates or subcontractors are not complying with the requirements of this Section 5.4(d) (Conduct of Global CDP and Joint CDP Activities) then the Parties shall via the JSC discuss and agree a remediation plan and Biotheus shall follow such plan so as to cure any non-compliance.
- (e) Each Party will maintain laboratories, offices, and all other facilities at its own expense and risk necessary to carry out its responsibilities under the Global CDP and Joint CDP. Each Party agrees to make its employees reasonably available at their

respective places of employment to consult with the other Party on issues arising during the performance of any Global CDP Activities and Joint CDP Activities. BioNTech and Biotheus will cooperate with each other in carrying out the Global CDP and Joint CDP.

5.5 **Clinical Trials in the Territory and Combination Trials**

Biotheus may not conduct any Clinical Trials or other studies in relation to the Licensed Products in the Territory except pursuant to the Joint CDP or as set out in this Section 5.5 (Clinical Trials in the Territory and Combination Trials). [***]

5.6 **Data Sharing**

To the extent permitted under Applicable Law, each Party hereby grants to the other Party (and its Affiliates and their respective licensees (in case of Biotheus) or Sublicensees (in case of BioNTech)), [***] the right to access the clinical and non-clinical data Controlled by that Party or its Affiliates and to cross-reference such data in the Regulatory Filings of the other Party or any of its Affiliates and their respective licensees (in case of Biotheus) or Sublicensees (in case of BioNTech) in the other Party's territory. [***] where Biotheus uses the clinical data generated by or on behalf of BioNTech in an Opted-Out Trial in Biotheus' Regulatory Filings with the Regulatory Authorities in the Retained Territory for the purpose of obtaining Regulatory Authorizations of a Licensed Product for the Opted-Out Indication with respect to such Opted-Out Trial, then such use by Biotheus shall be subject to reimbursement of [***] of BioNTech's costs incurred for generating such clinical data in an Opted-Out Trial for the relevant Opt-Out Indication, calculated in accordance with Section 5.3(e) (Eligible Development Costs for the Global CDP) multiplied by [***]. For the purpose of this Section 5.6 (Data Sharing), if BioNTech proposes to conduct a Global Trial for a given Indication and Biotheus does not share in the costs of such trial in accordance with Section 5.3 (Clinical Development Plans), then such Clinical Trial is an "**Opted-Out Trial**" and such Indication is an "**Opted-Out Indication**". If any BioNTech Background IP or BioNTech Foreground IP is incorporated in the Licensed Products Developed under the Global CDP in which Biotheus shares in the costs under such Global CDP in accordance with Section 5.3 (Clinical Development Plans) above, (a) BioNTech hereby grants to Biotheus a non-exclusive, sublicensable (through multiple tiers), [***] under such BioNTech Background IP or BioNTech

Foreground IP that is so incorporated by or on behalf of BioNTech; and (b) at Biotheus' request, BioNTech shall promptly transfer or cause its contractor(s) to transfer to Biotheus or its designated Third Party contractor all Know-How within such BioNTech Background IP or BioNTech Foreground IP, in each case (a) and (b) for the sole purpose of Biotheus Exploiting such Licensed Products in the Retained Territory.

5.7 Reporting

(a) Activities in the Territory

BioNTech agrees to keep Biotheus reasonably updated regarding BioNTech's material Development activities in the Territory with respect to each Licensed Product by providing [***] written updates in the JSC in accordance with Article 4 (Governance) and following dissolution of the JSC, to Biotheus [***] on a Licensed Product-by-Licensed Product basis a written summary of Development activities in the Territory carried out by BioNTech in [***] since the date of the last update. Such reports shall be the Confidential Information of BioNTech.

(b) Activities in the Retained Territory

Biotheus agrees to keep BioNTech reasonably updated regarding Biotheus' material Development activities in the Retained Territory with respect to each Licensed Product by (i) providing [***] written updates in the JSC in accordance with Article 4 (Governance) and following dissolution of the JSC, to BioNTech [***] in each [***] on a Licensed Product-by-Licensed Product basis a written summary of Development activities in the Retained Territory carried out by Biotheus in [***] since the date of the last update; (ii) submitting draft clinical development plans (including designs and protocols for proposed Clinical Trials) for comment by BioNTech in advance of commencing any clinical Development activities in respect of Licensed Products in the Retained Territory and considering in good faith any comments received from BioNTech; and (iii) promptly providing to BioNTech the results (including interim results) of any Clinical Trials relating to Licensed Products conducted by or on behalf of Biotheus in the Retained Territory. Such reports shall be the Confidential Information of Biotheus.

5.8 Cooperation

The Parties will collaborate in good faith to achieve smooth coordination and alignment between the Parties' Development and Commercialization activities with respect to Licensed Products in their respective territories subject and pursuant to the Global Commercialization Strategy.

6 REGULATORY AFFAIRS

6.1 Regulatory Filings

(a) Regulatory Filings in the Territory

Promptly upon request from BioNTech, Biotheus shall transfer all existing INDs relating to the Licensed Products in the Territory to BioNTech, along with all information and data required to support and maintain such INDs. Prior to such transfer of such INDs, Biotheus will maintain and manage such INDs in accordance with any written instructions received from BioNTech. In addition, until all existing INDs relating to the Licensed Products in the Territory have been transferred to BioNTech, Biotheus shall on written request from BioNTech file new INDs relating to the Licensed Products in the Territory in Indications specified by BioNTech. Promptly upon written request from BioNTech, Biotheus shall transfer all such new INDs to BioNTech, along with all information and data required to support and maintain such new INDs. Prior to such transfer of such new INDs, Biotheus will maintain and manage such new INDs in accordance with any written instructions received from BioNTech. BioNTech shall bear and reimburse Biotheus for all External Expenses incurred by or on behalf of Biotheus in connection with maintenance or management of such INDs relating to the Licensed Products in the Territory (including External Expenses approved in advance in writing by BioNTech and incurred for filing of new INDs at BioNTech's request) on or following the Execution Date until completion of the transfers of INDs.

Save for the transitional measures set out immediately above, BioNTech shall own and shall be responsible for the preparation and submission of all Regulatory Filings for all Licensed Products in the Territory at its own cost and expense and in its own name, including all communications, meetings and inspections with the Regulatory Authorities, save that

Biotheus shall, at its own cost and expense, provide (and use its reasonable efforts to procure that its Third Party CMOs provide) to BioNTech such support and input as BioNTech may from time to time request in writing, as may be reasonably necessary in respect of the preparation, filing and maintenance of Regulatory Filings for or inspections by a Regulatory Authority in relation to a Licensed Product in the Territory, including providing all documents, reports or other materials as may be necessary or useful for BioNTech or its Affiliates or their Sublicensees in dealing with such an inspection or preparing, filing and maintaining Regulatory Filings for the Licensed Products. Biotheus shall review and comment on any proposed material Regulatory Filings provided to it by BioNTech promptly and in good time before any deadlines and use Commercially Reasonable Efforts to assist BioNTech in its efforts to prepare and submit any Regulatory Filings to obtain, support, or maintain Regulatory Authorizations for any Licensed Product in the Territory; [***].

(b) **Regulatory Filings in the Retained Territory**

Biotheus shall own and shall be responsible for the preparation and submission of all Regulatory Filings for all Licensed Products in the Retained Territory at its own cost and expense and in its own name, including all communications, meetings and inspections with the Regulatory Authorities. The Parties shall discuss and co-operate with each other to ensure that such Regulatory Filings including but not limited to Regulatory Filings made to any cross-border data privacy regulators are made in sufficient time so that to the extent reasonably possible there are no delays to the ability of BioNTech to exercise its rights under the licenses granted to BioNTech by Section 3.1 (License Grants to BioNTech) of this Agreement, and that if there are delays they are minimised to the extent reasonably possible.

(c) **Right of Reference**

[***]

6.2 **PV Agreement**

Within [***] days of the Effective Date, the Parties shall agree in good faith and execute a pharmacovigilance agreement to govern the exchange of safety data with respect to the PM8002 Licensed Compound and PM8002 Licensed Product. Following the PM8003 Option

Exercise Date or the Preclinical Multispecific Option Exercise Date, if BioNTech determines that a pharmacovigilance agreement should be executed between the Parties to govern the exchange of safety data with respect to the PM8003 Licensed Compound and PM8003 Licensed Product or a Preclinical Multispecific Licensed Compound and Preclinical Multispecific Licensed Product as applicable, BioNTech will notify Biotheus and the Parties shall agree in good faith and execute such agreement within [***] days following such notification.

6.3 Data Privacy

If the Parties are going to share any patient data, patient records, safety data or other personal data, the Parties will transfer such data in accordance with Applicable Data Protection Law. To comply with the Applicable Data Protection Law, the Parties agree to enter into a separate data transfer agreement which sets out the data protection obligations of each Party including appropriate safeguards for cross-border transfers.

7 MANUFACTURING AND TECHNOLOGY TRANSFER

7.1 Manufacturing of PM8002 Licensed Products

(a) Prior to Technology Transfer of PM8002 Licensed Products

- (i) As promptly as reasonably practicable following the Execution Date, Biotheus shall conduct or procure that its existing CMO [***] conduct the CMC development work and Manufacturing preparatory work for the PM8002 Licensed Product the scope of which is [***].
- (ii) As promptly as reasonably practicable following the Execution Date and following discussion between the Parties and approval by BioNTech of the [***], Biotheus shall Manufacture and/or procure that [***] Manufacture a cGMP batch of PM8002 Licensed Product and carry out related activities the scope of which is [***], and [***] shall bear the costs of such work as listed on [***].

- (iii) As promptly as reasonably practicable following the Execution Date, Biotheus shall conduct and/or procure that [***] conduct the [***] for the PM8002 Licensed Product the scope of which is [***], and [***] shall bear the costs of such work as listed on [***].
- (iv) As promptly as reasonably practicable following the Qualification Date, Biotheus shall conduct and/or procure that [***] conduct the [***] activities for the PM8002 Licensed Product the scope of which is exclusively listed on [***], and the costs of such work shall be shared between the Parties [***] by [***] and [***] by [***].
- (v) As promptly as reasonably practicable following the Qualification Date, at the request of BioNTech in writing, Biotheus will procure that [***] conduct the [***] activities for the PM8002 Licensed Product the scope of which is exclusively listed on [***], and [***] shall bear the costs in relation to such work carried out on behalf of BioNTech as listed on [***].
- (vi) For clarity, if BioNTech requests Biotheus to conduct any work that is not expressly listed on Schedule 4 and Biotheus agrees to conduct such work, such work shall be conducted at [***] cost.
- (vii) To the extent that any of the activities set out in [***] relate to drug product for PM8002 Licensed Products then such activities shall continue to be carried out at [***].
- (viii) Following completion of Manufacturing Technology Transfer each Party shall [***] work in its respective territory.
- (ix) [***] following the Effective Date, the Parties will negotiate and execute a manufacturing development and clinical supply agreement and quality agreement pertaining to PM8002 Licensed Product upon mutually agreed upon terms and conditions, pursuant to which Biotheus will Manufacture and supply BioNTech's reasonable requirements for supply of PM8002 Licensed Product in the Territory for use in Clinical Trials. The Parties shall negotiate

in good faith and enter into such agreement within [***] days of the Effective Date.

(b) **Supplies of PM8002 Licensed Products for Clinical Trials**

- (i) From the Effective Date until successful completion of a Manufacturing Technology Transfer in respect of PM8002 Licensed Products pursuant to Section 7.2 (Manufacturing Technology Transfer for PM8002 Licensed Products), (A) Biotheus shall be responsible for having [***] complete the Manufacturing and release (it being understood that the release testing will be conducted first by Biotheus' qualified person, before BioNTech's qualified person conducts the final IMP release and BioNTech performs the sponsor release) of the PM8002 Licensed Products needed for the Global CDP and/or Joint CDP and/or any other Clinical Trials conducted by BioNTech in the Territory, as applicable; (B) BioNTech shall be responsible for reimbursing Biotheus' Cost of Goods without mark-up in connection with any PM8002 Licensed Product supplied to BioNTech under this Section 7.1(b) (Supplies of PM8002 Licensed Products for Global CDP and Joint CDP); and (C) for clarity, save for such Cost of Goods, Biotheus shall be responsible for bearing any other costs, fees or other sums associated with its existing CMO agreements. [***]

- (ii) In respect of Global Trials, on a Global Trial-by-Global Trial basis the Manufacture of PM8002 Licensed Products for each Global Trial will take place at a single Manufacturing site. For Global Trials commenced prior to successful completion of a Manufacturing Technology Transfer in respect of PM8002 Licensed Products pursuant to Section 7.2 (Manufacturing Technology Transfer for PM8002 Licensed Products), Biotheus shall be responsible for having [***] complete the Manufacturing and release of PM8002 Licensed Products for such Global Trials at a single Manufacturing site in accordance with Section 7.1(b)(i) (Supplies of PM8002 Licensed Products for Clinical Trials) above. For clarity, drug substance of PM8002 Licensed Compounds is Manufactured by Biotheus or its applicable Affiliates at Biotheus' location at Room 802-803, 8/F, Building A, Venture Outsourcing

Center, No.188 Tongsheng Road, Nantong City, Jiangsu Province, China and drug product of PM8002 Licensed Product is Manufactured by [***], in both cases, if approved and qualified by BioNTech for related manufacturing operations. For Global Trials commenced after successful completion of a Manufacturing Technology Transfer in respect of PM8002 Licensed Products pursuant to Section 7.2 (Manufacturing Technology Transfer for PM8002 Licensed Products), BioNTech shall be responsible for Manufacture of PM8002 Licensed Products for such Global Trials at a single Manufacturing site. In circumstances where BioNTech will be supplying Biotheus PM8002 Licensed Products for the purpose of a Global Trial pursuant to this Section 7.1(b)(ii) (Supplies of PM8002 Licensed Products for Clinical Trials), the Parties will negotiate and execute a manufacturing development and clinical supply agreement and quality agreement to cover such supply pursuant to which Biotheus will be responsible for reimbursing BioNTech's Cost of Goods [***] in connection with any PM8002 Licensed Products supplied to Biotheus under this Section 7.1(b)(ii) (Supplies of PM8002 Licensed Products for Clinical Trials).

7.2 **Manufacturing Technology Transfer for PM8002 Licensed Products**

Promptly following the Effective Date (unless otherwise requested by BioNTech), Biotheus will, at its cost and expense, transfer and at BioNTech's request cause its designated Third Party Manufacturer of the PM8002 Licensed Products to transfer the Manufacturing process and analytical methods for PM8002 Licensed Products to BioNTech, including transferring: all Licensed Know-How (including the information set out in Schedule 4 (Manufacturing and CMC Information)) necessary or useful to enable BioNTech or its Affiliates (or a Third Party designated on BioNTech's behalf) to Manufacture such PM8002 Licensed Products and to replicate the processes employed by or on behalf of Biotheus (including Biotheus' Third Party manufacturers) ("**Manufacturing Technology Transfer**"). For clarity, (i) Biotheus will only bear the costs and expenses in connection with the Manufacturing Technology Transfer to [***] designated by BioNTech, and all and any costs and expenses in connection with the Manufacturing Technology Transfer to [***] shall be borne by [***]; and (ii) the foregoing costs and expenses to be borne by Biotheus shall mean [***]. Within [***] days after the Effective Date, the Parties shall initiate good-faith discussion on a technology transfer plan that will set

out (a) the detailed activities and timelines required to achieve the Manufacturing Technology Transfer consistent with the Manufacturing Technology Transfer activities as set forth in [***], and (b) the on-site support and consultation to be provided by Biotheus, with a goal to adopt such technology transfer plan as soon as reasonably practicable following the Effective Date. The costs associated with the Manufacturing Technology Transfer borne by Biotheus shall include licensing and royalty payments, if any, due to Biotheus' existing cell line licensor and/or manufacturer under Biotheus' existing agreements regarding the Manufacture of PM8002 Licensed Products. If BioNTech desires to continue using in relation to the Manufacture of PM8002 Licensed Products the cell line licensed from [***] to Biotheus, BioNTech acknowledges that it will need to obtain a separate license from [***] for such purpose ("[***] License"). Biotheus will provide reasonable assistance to BioNTech to enable BioNTech to obtain such a [***] License and Biotheus shall reimburse BioNTech for any sums charged by [***] for the grant of such a license. For clarity, BioNTech shall be solely responsible for any and all payments (including but not limited to licensing and royalty payments) due to any cell line licensor and/or manufacturer that is not Biotheus's existing cell line licensor (or its successor) and/or existing manufacturer (or its successor) and is designated or engaged by BioNTech. Biotheus will maintain in force its existing agreements with [***] as listed on Schedule 8B attached hereto with respect to the Manufacture of PM8002 Licensed Products until such time as the Manufacturing Technology Transfer has been completed in accordance with this Section 7.2 (Manufacturing Technology Transfer for PM8002 Licensed Products). In addition to the CMC documents, Biotheus shall provide BioNTech or its external service provider with the following samples (including but not limited): Reasonable amounts of MCB (Master Cell Bank) and WCB (Working Cell Bank), analytical reference standards, process intermediates and any other samples that are required for a successful technology transfer of the Licensed Products. If BioNTech obtains a [***] License pursuant to this Section 7.2 (Manufacturing Technology Transfer for PM8002 Licensed Products), Biotheus agrees to provide reasonable assistance to BioNTech at Biotheus' cost to enable BioNTech to use the cell line to which such license relates including providing any letters of authorisation or assurances as to origin that BioNTech reasonably requests relating to any feed media for the cell line, and providing reasonable assistance to BioNTech for the purposes of responding to questions from any Regulatory Authority regarding any feed media for the cell line.

7.3 Following Completion of Manufacturing Technology Transfer for PM8002 Licensed Products

Following the successful completion of the Manufacturing Technology Transfer pursuant to Section 7.2 (Manufacturing Technology Transfer for PM8002 Licensed Products), and subject to any agreement between the Parties for supply of PM8002 Licensed Products, as between the Parties, BioNTech either on its own or through Affiliates or a Third Party manufacturer on its behalf, will have sole discretion over, and the sole right and responsibility for, at its sole cost and expense, Manufacture in respect of PM8002 Licensed Products for the Territory, including all activities related to developing the process, analytics and formulation for the Manufacture of clinical and commercial quantities of PM8002 Licensed Products, the production, Manufacture, processing, filling, finishing, packaging, labelling, inspection, testing, receiving, holding and shipping of PM8002 Licensed Products, or any raw materials or packaging materials with respect thereto, or any intermediate of any of the foregoing, including process and cost optimization, process qualification and validation, commercial Manufacture, stability, in-process and release testing, quality assurance and quality control. Notwithstanding the foregoing, the Parties will reasonably co-operate in order to align their manufacturing process (and/or those of their CMOs) for PM8002 Licensed Products in their respective territories.

7.4 Manufacturing of PM8003 Licensed Products and/or Preclinical Multispecific Licensed Products

From the PM8003 Option Exercise Date or the Preclinical Multispecific Option Exercise Date as applicable, the terms set out in Section 7.1 (Manufacturing of PM8002 Licensed Products), Section 7.2 (Manufacturing Technology Transfer for PM8002 Licensed Products) and Section 7.3 (Following Completion of Manufacturing Technology Transfer for PM8002 Licensed Products) will apply mutatis mutandis to the manufacture of the PM8003 Licensed Compound and the PM8003 Licensed Product or the Preclinical Multispecific Licensed Compound and the Preclinical Multispecific Licensed Product, as applicable.

7.5 BioNTech Audit Rights

- (i) For so long as Biotheus or its applicable Affiliate continues to Manufacture and supply any Licensed Product to BioNTech or to Manufacture any Licensed Product to be used in the Global Trials or Joint Trials, upon reasonable notice at least [***] days in advance of a proposed audit, during

regular business hours and under obligations of confidentiality, BioNTech (or its designees) shall be entitled to audit (either in person, online or on paper) and qualify Biotheus and all subcontractors or Third Parties used by Biotheus to Manufacture any Licensed Product that is supplied to BioNTech or used in the Global Trials or Joint Trials under this Agreement including Biotheus, its Affiliates, or any of their respective C(D)MOs or any other Third Party involved in such activities, and any activities relating to the creation or storage of any cell bank in connection with the Licensed Product that is supplied to BioNTech, to assess compliance with the applicable cGMP requirements and contractual agreements including but not limited to EudraLex Vol. 4 Part IV, and applicable EudraLex Annex 1 parts, US FDA 21 CFR Parts 11, 210, 211, WHO/ICH/PIC/s Regulations and applicable quality agreements agreed between the Parties. If such audit by BioNTech identifies any material non-compliance by Biotheus (including via its subcontractors) or its Affiliates (including via its subcontractors) with any of the foregoing then Biotheus shall take, and shall require its Affiliates or subcontractors to take, remedial actions to cure such non-compliance, and if such material non-compliance is confirmed to be an uncured material breach on the part of Biotheus pursuant to Section 13.2(b) (Termination for Breach), then the provisions of Section 13.2(b) (Termination for Breach) shall apply. For clarity, any uncured failure to qualify on the part of Biotheus or [***] shall be deemed an alleged uncured material breach on the part of Biotheus pursuant to Section 13.2(b) (Termination for Breach) and the provisions of Section 13.2(b) (Termination for Breach) shall apply.

- (ii) For so long as Biotheus or its applicable Affiliate continues to conduct activities assigned to it under the Global CDP or Joint CDP and/or any other activities relevant for Clinical Trials conducted by BioNTech in the Territory, as applicable, upon reasonable notice at least [***] days in advance of a proposed audit, during regular business hours and under obligations of confidentiality, BioNTech (or its designees) shall be entitled to audit (either in person, online or on paper) and qualify Biotheus and all subcontractors or Third Parties used by Biotheus to carry out activities under the Global CDP or Joint CDP and/or activities relevant for Clinical Trials conducted by

BioNTech in the Territory, as applicable, including (a) Biotheus, its Affiliates, or any of their respective CROs or any other Third Party involved in clinical Development activities, testing activities (including clinical and preclinical testing) and any other activities under the Global CDP or Joint CDP; and (b) any of Biotheus' or its Affiliates' clinical sites, as selected by BioNTech in its sole discretion, in each case of the foregoing (a) and (b), to assess compliance with all GxPs including but not limited to applicable cGCP requirements and all matters arising from any pharmacovigilance agreement agreed between the Parties pursuant to Section 6.2 (PV Agreement). If such audit by BioNTech identifies any material non-compliance by Biotheus (including via its subcontractors and clinical sites) or its Affiliates (including via its subcontractors and clinical sites) with any of the foregoing then Biotheus' shall take, and shall require its Affiliates, subcontractors or clinical sites to take, remedial actions to cure such non-compliance, and if such material non-compliance is confirmed to be an uncured material breach on the part of Biotheus pursuant to Section 13.2(b) (Termination for Breach), then the provisions of Section 13.2(b) (Termination for Breach) shall apply.

- (iii) In addition if BioNTech identifies any material non-compliance or failure to qualify on the part of any relevant Third Party pursuant to this Section 7.5 (BioNTech Audit Rights) Biotheus shall at BioNTech's request terminate any agreement with such Third Party.

8 FINANCIAL TERMS

BioNTech's payment obligations set out in the Article 8 (Financial Terms) are conditional on and subject to the completion of a successful audit by BioNTech to BioNTech's reasonable satisfaction of, and at BioNTech's discretion also qualification of, both Biotheus and [***] pursuant to Section 7.5(i) (BioNTech Audit Rights) (the date on which BioNTech is so satisfied being the "**Qualification Date**"). BioNTech shall commence such audit (which may be conducted by a Third Party acting for BioNTech) as soon as reasonably possible following the Execution Date but in no event later than [***], and shall notify Biotheus promptly in writing with the results of such audit and, as applicable, qualification following BioNTech's completion of the audit and, as applicable, qualification, both of which shall take place no later than [***].

If such audit or, as applicable, qualification, identify any non-compliance by Biotheus or [***], Biotheus shall take such steps or procure that [***] takes such steps to cure such non-compliance. If either Biotheus or [***] does not successfully complete such audit and, as applicable, qualification to BioNTech's reasonable satisfaction, BioNTech shall be entitled to terminate this Agreement without further liability pursuant to Section 13.2(a) (Termination for Convenience by BioNTech or Biotheus). If BioNTech does not complete such audit and, as applicable, qualification and notify Biotheus of the results thereof in writing on or before [***], Biotheus shall be entitled to terminate this Agreement without further liability pursuant to Section 13.2(a) (Termination for Convenience by BioNTech or Biotheus). For clarity, no payments shall be due from BioNTech to Biotheus under this Agreement unless and until the Qualification Date is achieved, except that if this Agreement is terminated as a whole by Biotheus pursuant to Section 13.2(a) (Termination for Convenience by BioNTech or Biotheus), then BioNTech shall reimburse Biotheus for [***] of any costs and expenses incurred by Biotheus in conducting the activities requested by BioNTech in writing pursuant to Section 7.1(a) (iii) (Prior to Technology Transfer of PM8002 Licensed Products). [***]

8.1 **Upfront Payment**

BioNTech will pay to Biotheus a non-refundable (except as provided in this Agreement), non-creditable upfront payment of fifty five million United States Dollars (\$55,000,000) (the "**Upfront Payment**"). The Upfront Payment shall become due and be paid by BioNTech to Biotheus no later than [***] days after BioNTech's receipt of an invoice from Biotheus, which invoice shall include the relevant PO number provided by BioNTech and be sent to BioNTech at [***]. Such invoice may be issued on or following the Qualification Date.

8.2 **Technology Transfer Payment**

BioNTech will pay to Biotheus a payment of ten million United States Dollars (\$10,000,000) ("**Technology Transfer Payment**") upon successful completion of the Manufacturing Technology Transfer for PM8002 Licensed Products pursuant to Article 7 (Manufacturing and Technology Transfer) provided that such sum may be reduced in accordance with the provisions of Section 7.2 (Manufacturing Technology Transfer for PM8002 Licensed Products). The Technology Transfer Payment shall become due and be paid by BioNTech to Biotheus no later than [***] days after BioNTech's receipt of an invoice from Biotheus, which

invoice shall include the relevant PO number provided by BioNTech and be sent to BioNTech at [***]. Such invoice may be issued on or following the date the Manufacturing Technology Transfer for PM8002 Licensed Product is successfully completed pursuant to Article 7 (Manufacturing and Technology Transfer) as evidenced by a technology transfer report signed by the Parties (it being agreed and understood that the Parties shall sign such report if the successful completion of the Manufacturing Technology Transfer for PM8002 Licensed Products, as defined below, has occurred). For the purpose of this Section 8.2 (Technology Transfer Payment), the "successful completion of the Manufacturing Technology Transfer for PM8002 Licensed Products" shall mean [***]. Each Party shall use reasonable efforts to comply with any timelines agreed in the transfer plan.

8.3 **Development and Approval Milestone Payments for Licensed Products**

Following the Effective Date, BioNTech will pay Biotheus the amounts set forth in Table 8.3 below (each a "**Development Milestone Payment**") no later than [***] days after receipt of an invoice from Biotheus (except that for the Development Milestone Payment for Development Milestone Event Number 1 in the table below, such payment shall be payable by BioNTech within [***] Business Days after receipt of an invoice from Biotheus, which invoice shall be issuable after [***]. An invoice shall be issuable by Biotheus after the first occurrence of each milestone event described below (each, a "**Development Milestone Event**") triggered by the first Licensed Product [***], to achieve such Development Milestone Event. BioNTech shall notify Biotheus in writing within [***] days of the achievement of each of the Development Milestone Events set forth in Table [***], whether the relevant milestone is achieved by BioNTech, its Affiliates or their respective Sublicensees. Irrespective of the number of

Licensed Products that has achieved a Development Milestone Event, the Development Milestone Payments shall be payable once only. [***]

For the purposes of Development Milestone Event 1 in the table below, [***].

[***]

8.4 **Sales Milestone Payments for Licensed Products**

BioNTech will pay to Biotheus the amounts set forth in Table [***] below (each a **"Sales Milestone Payment"**) no later than [***] days after receipt of an undisputed invoice from Biotheus, which invoice shall be issuable after the first achievement of each event described below (each a **"Sales Milestone Event"**) triggered by [***]. BioNTech shall notify Biotheus in writing within [***] days of the end of the [***] in which the Sales Milestone Events set forth in Table [***] are achieved, whether the relevant milestone is achieved by BioNTech, its Affiliates or their respective Sublicensees. Irrespective of the number of Licensed Products that have achieved a Sales Milestone Event and how many times the same Sales Milestone Event is achieved, the Sales Milestone Payments shall be payable once only.

[***]

(a) **Achievement of Multiple Sales Milestones**

If two or more Sales Milestone Events are achieved in the same [***], then BioNTech will pay the Sales Milestone Payment in respect of the first such Sales Milestone Event to occur in that [***] when such milestone payment falls due, and the second Sales Milestone Event will be treated as having been achieved on the first day of the subsequent [***]. In the event that a further Sales Milestone Event occurs in that subsequent [***], such further Sales Milestone Event will be treated as having been achieved on the first day of the next [***], and so forth.

8.5 Royalty Payments

(a) Royalty Rates for Licensed Products

Subject to the provisions of Section 8.5(b) (Adjustments to Royalties) and Sections 8.6 (Improved Licensed Products), 8.7 (PM8003 Licensed Products) or 8.8 (Preclinical Multispecific Licensed Products) in relation to Improved Licensed Products, PM8003 Licensed Products and/or Preclinical Multispecific Licensed Products, [***], BioNTech will pay to Biotheus tiered royalties based on annual Net Sales of a Licensed Product (on a Licensed Product-by-Licensed Product basis) by BioNTech and its Affiliates and its Sublicensees in a Calendar Year in the Territory during the Royalty Term for each such Licensed Product in such country at the rates set forth in Table [***] below. The royalty payments made pursuant to this Section 8.5(a) (Royalty Rates for Licensed Products), the "**Royalties**" and the rates set forth in Table [***], the "**Royalty Rates**".

[***]

(b) Adjustments to Royalties

(i) Biosimilar Products

[***]

(ii) Compulsory Licenses

[***]

(iii) Third Party Licenses

- (A) If in the absence of a license from a Third Party to any Patent Rights, the Development, Manufacture or Commercialization of a Licensed Product by BioNTech, its Affiliates or its or their Sublicensees would infringe such Patent Rights controlled by a Third Party and BioNTech obtains or prior to the Effective Date has obtained a license to such

Third Party Patent Rights ("**Additional Third Party Licenses**"), BioNTech would be solely responsible for, as applicable, negotiating, obtaining and maintaining any such Additional Third Party Licenses but would not be obliged to do so.

(B) [***]

(C) Notwithstanding any provision to the contrary in this Agreement, Biotheus will remain solely responsible for the payment of any royalty, milestone, and other payment obligations, if any, due to Third Parties in connection with any agreement between Biotheus or its Affiliate relating to the Licensed IP including the Biotheus In-Licenses.

(iv) **No Valid Claim**

On a Licensed Product-by-Licensed Product and country-by-country basis, if there is no Valid Claim of a Licensed Patent Right Covering such Licensed Product in such country but such Licensed Product is still the subject of Regulatory Exclusivity in such country, then the Royalty Rates for Royalties due to Biotheus pursuant to Section 8.5(a) (Royalty Rates for Licensed Products) with respect to such Licensed Product in such country for such Calendar Quarter shall be reduced by [***].

(c) **Cumulative Effect of Royalty Reductions**

On a [***] basis, in no event will the royalty reductions for a Licensed Product permitted under Section [***] in relation to Improved Licensed Products, PM8003 Licensed Products and/or Preclinical Multispecific Licensed Products reduce the Royalties due to Biotheus for such Licensed Product pursuant to Section 8.5(a) (Royalty Rates for Licensed Products) in a country in a given [***] in the aggregate by [***] of the amount otherwise payable. In the event that BioNTech would, but for the restriction set forth in this Section 8.5(c) (Cumulative Effect of Royalty Reductions), have the right to reduce the Royalties due to Biotheus for a Licensed Product pursuant to Section 8.5(a) (Royalty Rates for Licensed Products) in a country in a

[***] under Section 8.5(a) (Royalty Rates for Licensed Products) to [***] then any such unused reduction may be carried forward and used as a credit in one or more future [***] for such Licensed Product in the same country, and such unused reduction shall be carried forward until such time as such unused credit has been exhausted [***].

8.6 Improved Licensed Products

Following the date that the Improved Licensed Product Conditions are met, (a) the applicable remaining milestone(s) that have not previously been triggered by another Licensed Product but are triggered by an Improved Licensed Product and royalty payments payable for such Improved Licensed Product under Sections 8.3 (Development and Approval Milestone Payments for Licensed Products) and 8.5 (Royalty Payments for Licensed Products) above shall all be reduced by [***] of the sums otherwise payable in respect of such Improved Licensed Product; and (b) the applicable Sales Milestone Payments payable for such Improved Licensed Product under Section 8.4 (Sales Milestone Payments for Licensed Products) shall be reduced in proportion to the annual Net Sales of such Improved Licensed Product as a proportion of overall annual Net Sales of Licensed Products. For example, where there are two Licensed Products: Licensed Product A (a Bispecific Antibody in protein form) and Licensed Product B (a Bispecific Antibody in nucleotide form) and the annual Net Sales of both Licensed Products combined is \$[***] with each Licensed Product contributing [***] of Net Sales then the \$[***] Sales Milestone Payment that would otherwise be due pursuant to Section 8.4 (Sales Milestone Payments for Licensed Products) shall be reduced as follows:

[***]

For clarity, no milestones that have previously been triggered by another Licensed Product pursuant to Section 8.3 (Development and Approval Milestone Payments for

Licensed Products) will be due a second time if such Improved Licensed Product achieves the relevant Milestone Event.

8.7 PM8003 Licensed Products

Following the PM8003 Option Exercise Date, (a) the applicable remaining milestone(s) that have not previously been triggered by another Licensed Product but are triggered by a PM8003 Licensed Product and royalty payments payable for such PM8003 Licensed Product under Sections 8.3 (Development and Approval Milestone Payments for Licensed Products), 8.4 (Sales Milestone Payments for Licensed Products) and 8.5 (Royalty Payments for Licensed Products) above shall all be reduced by [***] of the sums otherwise payable in respect of such PM8003 Licensed Product. For clarity, no milestones that have previously been triggered by another Licensed Product pursuant to Section 8.3 (Development and Approval Milestone Payments for Licensed Products) will be due a second time if such PM8003 Licensed Product achieves the relevant Milestone Event.

8.8 Preclinical Multispecific Licensed Products

Following the Preclinical Multispecific Option Exercise Date, (a) the applicable remaining milestone(s) that have not previously been triggered by another Licensed Product but are triggered by a Preclinical Multispecific Licensed Product and royalty payments payable for such Preclinical Multispecific Licensed Product under Sections 8.3 (Development and Approval Milestone Payments for Licensed Products), 8.4 (Sales Milestone Payments for Licensed Products) and 8.5 (Royalty Payments for Licensed Products) above shall all be reduced by [***] of the sums otherwise payable in respect of such Preclinical Multispecific Licensed Product. For clarity, no milestones that have previously been triggered by another Licensed Product pursuant to Section 8.3 (Development and Approval Milestone Payments for Licensed Products) will be due a second time if such Preclinical Multispecific Licensed Product achieves the relevant Milestone Event.

8.9 Combinations with In-Licensed BioNTech Products

In the event that a milestone under Section 8.3 (Development and Approval Milestone Payments for Licensed Products) is triggered by (a) [***]; or (b) [***], then the respective

milestone payment will be payable for such Licensed Product under Section 8.3 (Development and Approval Milestone Payments for Licensed Products) above shall be reduced [***] of the sums otherwise payable in respect of such Licensed Product; [***].

8.10 **Royalty Reports; Payments**

Commencing on the First Commercial Sale of a Licensed Product and for so long as Royalties are due under this Agreement, no later than [***] days after the end of each [***], BioNTech will provide to Biotheus a written report (each, a "**Royalty Report**"), which Royalty Report will set forth: [***]. All Royalty Reports will be the Confidential Information of BioNTech. BioNTech will make all Royalty payments for each [***] no later than [***] days after receipt of an invoice from Biotheus, which invoice shall be provided promptly following the receipt by Biotheus of each Royalty Report from BioNTech pursuant to this Section 8.10 (Royalty Reports; Payments). [***]

8.11 **Other Payments**

Subject to the terms and conditions of this Agreement, each Party will pay to the other Party any other undisputed amounts due under this Agreement no later than [***] days after receipt of the relevant invoice. [***]

8.12 **Records and Audits**

(a) **Books and Records**

Each Party will (a) keep complete, true, and accurate books and records in accordance with its Accounting Standards in relation to this Agreement, including in relation to, Eligible Development Costs, Cost of Goods, and Net Sales of Licensed Products in sufficient detail to enable amounts owed or payable to the other Party hereunder to be determined; and (b) maintain such books and records for at least [***] following the [***] to which they pertain. Each Party (the "**Auditing Party**") may, upon written request, cause an internationally-recognized independent "Top Four" accounting firm (the "**Auditor**"), that is reasonably acceptable to the other Party (the "**Audited Party**") to inspect the relevant records of such Audited Party and its

Affiliates to verify the payments made and amounts reported by the Audited Party and the related reports, statements, and books of accounts, as applicable.

(b) **Audit Procedure**

Before beginning its audit, the Auditor will execute a written agreement acceptable to the Audited Party by which the Auditor agrees to keep confidential all information reviewed during the audit, which agreement will contain terms of non-disclosure and non-use no less stringent than those set forth in this Agreement. The Auditor will have the right to disclose to the Auditing Party only its conclusions regarding any payments owed under this Agreement. Each Party and its Affiliates will make their records available for inspection by the Auditor during regular business hours at such place or places where such records are customarily kept, upon receipt of reasonable advance notice from the Auditing Party. The records will be reviewed solely to verify the accuracy of the Audited Party's Royalties and other payment obligations and compliance with the financial terms of this Agreement.

(c) **Frequency; Overpayments and Underpayments**

Such inspection right will not be exercised more than once in any [***] and not more than once with respect to records covering any specific period of time. In addition, the Auditing Party will only be entitled to audit the books and records of the Audited Party for the [***] prior to the [***] in which the audit request is made. The Auditing Party agrees to hold in strict confidence all information received and all information learned in the course of any audit or inspection, except to the extent necessary to enforce its rights under this Agreement or to the extent required to comply with any Applicable Law or judicial order. The Auditor will provide its audit report and the conclusions of its determination to the Audited Party at the time such report is provided to the Auditing Party before it is considered final. In the event that the final result of the inspection reveals an underpayment or overpayment by either Party, the underpaid or overpaid amount will be settled promptly. The Auditing Party will pay for such inspections, as well as its expenses associated with enforcing its rights with respect to any payments hereunder; *provided*, that if an underpayment of more than [***] of the

total payments due hereunder for the applicable year is discovered, then the fees and expenses charged by the Auditor will be paid by Audited Party.

8.13 **Currency of Payment**

All amounts to be paid pursuant to this Agreement will be paid in United States Dollars. When conversion of payments from any foreign currency is required to be undertaken by BioNTech, the United States Dollar equivalent will be calculated using BioNTech's then-current standard exchange rate methodology as applied in its external reporting for the conversion of foreign currency sales into United States Dollars.

8.14 **Late Fees**

If any payment due to either Party under this Agreement is not paid when due, then such paying Party shall pay interest thereon (before and after any judgment) at an [***] rate [***] of [***], such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest.

8.15 **Currency Restrictions**

In the event that, by reason of Applicable Law in any country, it becomes impossible or illegal for a Party to transfer, or have transferred on its behalf, payments owed to the other Party hereunder, such Party will promptly notify the other Party of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country to the credit of the other Party in a recognized banking institution designated by the other Party or, if none is designated by the other Party within a period of [***] days, in a recognized banking institution selected by the transferring Party, as the case may be, and identified in a written notice given to the other Party.

8.16 **No Refunds; Offsets**

Except as expressly set forth under this Agreement, all payments under this Agreement will be irrevocable, non-refundable, and non-creditable.

8.17 **Withholding Taxes**

The Royalties, milestone payments, and other amounts payable by a Party to the other Party pursuant to this Agreement (" **Payments**") shall not be reduced on account of Taxes unless required by Applicable Law. The receiving Party alone shall be responsible for paying any and all Taxes (other than withholding Taxes required by Applicable Law to be paid by the paying Party) levied on account of, or measured in whole or in part by reference to, any Payments it receives. Either Party (a "**Withholding Party**") shall deduct or withhold from the Payments due to the other Party (a "**Non-Withholding Party**") any Taxes that it is required by Applicable Law to deduct or withhold. If, however, the Non-Withholding Party is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, then it may deliver to the Withholding Party or the appropriate Governmental Authority (with the assistance of the Withholding Party to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the Withholding Party of its obligation to withhold tax, and the Withholding Party shall apply the reduced rate of withholding, or dispense with withholding, as the case may be, PROVIDED THAT the Withholding Party has received evidence, in a form reasonably satisfactory to the Withholding Party, of the Non-Withholding Party's delivery of all applicable forms prior to the time that the Payments are due and the respective approval from the authorities. If the Withholding Party withholds any Taxes from the Payments while the Non-Withholding Party is entitled under any applicable tax treaty to a reduction of the rate of, or the elimination of, applicable withholding tax, then the Withholding Party shall cooperate with the Non-Withholding Party with respect to any documentation required by the appropriate Governmental Authority or reasonably requested by the Non-Withholding Party to secure a reduction of the rate of, or the elimination of, the applicable Taxes withheld. Notwithstanding anything to the contrary contained herein, BioNTech's reimbursement of the Eligible Development Costs shall not be deemed to be the Payments or subject to any deduction or withholding of Taxes.

8.18 **Indirect Taxes**

Notwithstanding anything to the contrary contained in this Article 8 (Financial Terms) or elsewhere in this Agreement, the following shall apply with respect to Indirect Taxes. All Payments are stated exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in

respect of any Payments, then the paying Party shall pay such Indirect Taxes at the applicable rate in respect of any such Payments following the receipt, where applicable, of an Indirect Taxes invoice issued in the appropriate form by the receiving Party in respect of those Payments, such Indirect Taxes to be payable on the due date of the payment of the Payments to which such Indirect Taxes relate. The Parties shall issue invoices for all goods and services supplied under this Agreement consistent with Indirect Tax requirements, and to the extent any invoice is not initially issued in an appropriate form, the Parties shall cooperate to provide such information or assistance as may be necessary to enable the issuance of such invoice consistent with Indirect Tax requirements. Biotheus shall provide any documents necessary for tax and customs clearance in a format as reasonably required and specified by BioNTech.

9 INTELLECTUAL PROPERTY

9.1 Ownership of Inventions

(a) Ownership

(i) Background IP

As between the Parties, and subject to the licenses granted under this Agreement, (i) BioNTech and its Affiliates shall solely own (or retain ownership of) all rights, title and interests in and to any of the BioNTech Background IP, (ii) Biotheus and its Affiliates shall solely own (or retain ownership of) all rights, title and interests in and to any of the Licensed IP and (iii) each Party or its Affiliates, as applicable, shall solely own (or retain ownership of) any other Know-How and Inventions that are developed by or on behalf of that Party outside and independently of the activities under this Agreement.

(ii) Foreground IP

Subject to Section 5.6 (Data Sharing), as between the Parties, [***].

(b) **Disclosure**

During the Term, each Party will promptly disclose to the other Party all Inventions that it develops or invents in the course of carrying out activities pursuant to the Joint CDP or Global CDP, whether solely or jointly with others (in any event, prior to the filing of any patent application with respect to such Inventions), including all invention disclosures or other similar documents submitted to such Party by its or its Affiliates' employees, agents, or independent contractors relating thereto. Each Party will also respond promptly to reasonable requests from the other Party for additional information relating to such Inventions.

(c) **Personnel Obligations**

Each employee, agent, or independent contractor of a Party or its respective Affiliates or Sublicensees performing work under this Agreement will, prior to commencing such work, be bound by invention assignment obligations, including: (a) promptly reporting any invention, discovery, process or other Intellectual Property Rights; (b) presently assigning to the applicable Party all of his or her rights, title and interests in and to any invention, discovery, process, or other Intellectual Property Rights; (c) cooperating in the Prosecution and Maintenance and enforcement of any patent and patent application; and (d) performing all acts and signing, executing, acknowledging, and delivering any and all documents required for effecting the obligations and purposes of this Agreement. It is understood and agreed that such invention assignment agreement need not reference or be specific to this Agreement.

9.2 **Patent Prosecution.**

(a) **PM8002 Licensed Products**

[***]

(b) **PM8003 Licensed Products**

[***]

(c) **Preclinical Multispecific Licensed Products**

[***]

(d) [***]

(e) [***]

(f) [***]

(g) [***]

(h) [***]

(i) [***]

9.3 **Patent Enforcement**

(a) **Notification**

Each Party will promptly notify the other in the event of any actual, likely or suspected infringement of [***], including any Infringement that arises as a result of the making, using, offering to sell, selling, or importing of a product that would be competitive with a Licensed Product and that is Directed to the same Target as such Licensed Product (a “**Competitive Infringement**”). In addition, each Party will promptly notify the other in the event such Party becomes aware of any action by a Third Party for a declaration that any of the Product-Specific Patent Rights are not infringed or are invalid, or unenforceable. In all cases, each Party will provide any available evidence of such Infringement or other conduct with such notification.

(b) **Infringement Actions**

[***]

(c) **Collaboration**

Each Party will provide the other Party with reasonable assistance in the enforcement action brought under this Section 9.3 (Patent Enforcement), at the enforcing Party's request and expense, including to be named in such action if required by, or desirable under, Applicable Laws to pursue such action. The enforcing Party will keep the non-enforcing Party regularly informed of the status and progress of such enforcement efforts, will reasonably consider the non-enforcing Party's comments on any such efforts, including determination of litigation strategy and filing of material papers to the competent court. The non-enforcing Party will be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but will at all times cooperate with the enforcing Party in good faith.

(d) **Expenses and Recoveries**

The enforcing Party will be solely responsible for any expenses (including attorneys' fees and costs) incurred by the enforcing Party as a result of such claim, suit, or action. If the enforcing Party recovers monetary damages in such claim, suit, or action, then such recovery will be allocated first to the reimbursement of any expenses incurred by the enforcing Party in bringing suit and the reimbursement of any expenses incurred by the non-enforcing Party in such litigation, allocated in proportion to the amounts the Parties have incurred, and any remaining amounts shall be treated as Net Sales for the purposes of this Agreement.

9.4 [***]

9.5 **Use of Trademarks**

[***]

9.6 **Marking**

Each Party shall, and shall cause its Affiliates and their Sublicensees to, mark the Licensed Products sold under this Agreement with the number of each issued and granted Licensed Patent Right that applies to the relevant Licensed Products if required by Applicable Law.

10 CONFIDENTIALITY

10.1 Confidential Information

(a) General

Each Party (the "**Receiving Party**") will maintain all Confidential Information disclosed to it or its representatives by or on behalf the other Party (the "**Disclosing Party**") in confidence during the Term of this Agreement and for a period of [***] years after the expiration or termination of this Agreement; provided that any Confidential Information of either Party that constitutes a trade secret will continue to be subject to the terms of this 10.1 (Confidentiality) in perpetuity, so long as such information remains a trade secret. Each Party will use all such disclosed Confidential Information of the Disclosing Party only to the extent necessary for purposes of this Agreement, including exercising the licenses and rights hereunder and will not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except as permitted under this Agreement. The Parties will agree a policy for managing trade secrets provided by a Party under this Agreement. Each Party will notify the other Party promptly on discovery of any unauthorized use or disclosure by a Party of the other Party's Confidential Information, including the other Party's trade secrets. Product-Specific Know-How is the Confidential Information of both Parties provided that (i) other than for the purposes permitted in Section 10.1(d) (Permitted Disclosures) below and Section 10.3 (Publications and Presentations) below, Biotheus shall not disclose the Product-Specific Know-How to a Third Party or otherwise publish the Product-Specific Know-How without the prior written consent of BioNTech and (ii) other than for the purposes permitted in Section 10.1(d) (Permitted Disclosures) below and Section 10.3 (Publications and Presentations) below, BioNTech shall not disclose the Product-Specific Know-How to a Third Party or otherwise publish the Product-Specific Know-How without the prior written consent of Biotheus.

(b) **Confidential Information of Each Party**

Except as otherwise specified in this Agreement, all information disclosed prior to the Execution Date pursuant to the Confidential Disclosure Agreement between the Parties dated [***] (the "**Confidentiality Agreement**") by Biotheus to BioNTech will be Confidential Information of Biotheus and by BioNTech to Biotheus will be Confidential Information of BioNTech. During the Term, Biotheus shall not disclose to a Third Party any Licensed Know-How that is specific to a Licensed Compound or Licensed Product without the prior written consent of BioNTech.

(c) **Exceptions to Confidentiality**

The following information will not be Confidential Information of the Disclosing Party and accordingly, the obligations of each Receiving Party imposed by Section 10.1(a) (General) will not apply to any such information that: (a) was known to the Receiving Party without an obligation to keep such information confidential prior to the Execution Date other than as a result of disclosure under any other agreement between the Parties, including the Confidentiality Agreement (as demonstrated by documentary evidence); (b) is or becomes generally available to the public through means other than an unauthorized disclosure by the Receiving Party, its Affiliates, or any of its agents to whom it or they disclosed such information; (c) was or subsequently is disclosed to the Receiving Party without restriction by a Third Party having a *bona fide* right to disclose such Confidential Information without breaching any obligation to the Disclosing Party; or (d) is developed independently by the Receiving Party without use of or reference to any of the Disclosing Party's Confidential Information.

(d) **Permitted Disclosures**

(i) **General**

Notwithstanding any provision to the contrary set forth in this Section 10.1 (Confidential Information), each Receiving Party may use and make disclosures of Confidential Information of the Disclosing Party: (i) to its Affiliates, and the Receiving Party's or its Affiliates' employees, directors,

agents, consultants, or advisors, or actual or potential Sublicensees to the extent necessary for the potential or actual performance of its obligations or exercise of its licenses and other rights under this Agreement, in each case, who are under an obligation of confidentiality and non-use with respect to such information that is no less stringent than the terms of this Agreement; (ii) subject to Section 10.1(a) (General), to patent offices in any country in which Patent Rights are sought for purposes of filing and prosecuting any applications for any Patent Rights which may be filed in accordance with this Agreement or defending any such Patent Rights in challenges to the validity of such Patent Rights as contemplated by this Agreement; (iii) to Regulatory Authorities or Governmental Authorities as necessary to pursue Development, Commercialization, Manufacturing, Regulatory Filing, or Marketing Authorization of Licensed Products; provided, that such Confidential Information will be disclosed only to the extent reasonably necessary to do so, and where permitted, subject to confidential treatment; (iv) to the extent required to comply with Applicable Law or a court or administrative order, including of any national regulatory agency or listing authority; or (v) to any tax authority, in each case, to the extent applicable to such Party at such time; provided, however, that in respect of part (iv) the Party who is required to make such disclosure (A) provides the other Party with reasonable prior written notice, (B) coordinates with the other Party with respect to the wording and timing of any such disclosure and affords the other Party an opportunity to oppose or limit, or secure confidential treatment for such required disclosure, (C) if unsuccessful in its efforts pursuant to clause (B), takes all reasonable and lawful actions to obtain confidential treatment for such disclosure, and (D) discloses the minimum amount and scope of the Confidential Information necessary to comply with Applicable Law. Notwithstanding the foregoing, any Confidential Information so disclosed will remain subject to the terms of this Agreement.

(ii) **Agreement**

Solely with respect to the terms of this Agreement, either Party may disclose the terms of this Agreement to any *bona fide* actual or prospective acquirers,

underwriters, investors, lenders or other financing sources (including in connection with any royalty monetization transaction) and any *bona fide* actual or prospective licensors, Sublicensees, licensees, or strategic partners and to employees, directors, agents, consultants, and advisers of such Third Party, who are under an obligation of confidentiality with respect to such information that is no less stringent than the terms of this Agreement, and PROVIDED THAT such Confidential Information will be disclosed only to the extent reasonably necessary to evaluate the proposed transaction or perform its obligations or exercise its rights granted under the applicable agreement.

(e) **Publicity**

At a date to be agreed between the Parties following the Execution Date [***], Biotheus may issue a press release in the form agreed and set out in Schedule 9 (Biotheus Press Release). Except for the foregoing and as required by Applicable Law, legal process or stock exchange rules, Biotheus shall not issue a press or news release or make any similar public announcement related to the execution or terms of this Agreement, the conduct of Development activities or the Commercialization of Licensed Products without the prior written consent of BioNTech. For clarity, any such press or news release or similar public announcement by Biotheus shall take into account any comments or edits required by BioNTech as a condition of approval. BioNTech will in its discretion be entitled to make press or news releases or similar public announcements related to the conduct of Development activities or the Commercialization of Licensed Products in the Territory, provided that BioNTech shall provide Biotheus with a draft of such announcement in advance and shall consider any comments received from Biotheus in good faith. For clarity if [***] wishes to make such an announcement regarding the execution or terms of this Agreement [***] prior written consent shall be required. In the event of termination of this Agreement for any reason, if either Party intends to make a public announcement related to such termination or the public disclosure of such termination is required under the Applicable Law or the rules of a stock exchange on which the securities of either Party (or any controlling Affiliate of such Party) are listed (or to which an application for listing has been submitted), the Parties shall cooperate in good faith to coordinate public announcement or disclosure, if any, of such termination and the reasons

therefor. The principles to be observed in such disclosures shall be accuracy, compliance with Applicable Law, the rules of the applicable stock exchange and regulatory guidance documents, and reasonable sensitivity to potential negative investor reaction to such news.

10.2 **No Use of Name**

Subject to the terms of this Agreement, neither Party will use the name or Trademarks of the other Party in any promotional materials or advertising without the prior written consent of the other Party, except as provided under this Agreement or required by Applicable Law, in which case the Party disclosing such name or Trademarks will give advance notice of such use and otherwise comply with Section 11.3(a) (Compliance with Law). [***]

10.3 **Publications and Presentations**

BioNTech shall have the sole right, either itself or through its Affiliates or Sublicensees, to present or publish the results of, or scientific information relating to, any activities under this Agreement PROVIDED THAT prior to the [***] the Parties will agree through the JSC on the content of any publications relating to the [***] and/or [***]. Biotheus shall not make any publication or presentation relating to a Licensed Compound or Licensed Product without the prior written consent of BioNTech. If, in accordance with the requirements and limitations of this Section 10.3 (Publications and Presentations), a Party desires to publicly present or publish results or scientific information relating to a Licensed Compound or Licensed Product which publication contains the Confidential Information of the non-publishing Party, prior to doing so, the publishing Party will provide non-publishing Party with drafts of proposed abstracts, manuscripts or summaries of presentations that include such results or information. The non-publishing Party will respond no later than [***] days after receipt of such proposed publication or presentation or such shorter period as may be agreed to by the Parties. The publishing Party will delay any such proposed publication or presentation for a period up [***] days after the non-publishing Party receives such proposed publication or presentation to permit the non-publishing Party to make filings for patent protection and will otherwise remove its Confidential Information identified by the non-publishing Party in such publication or presentation. The Parties agree to acknowledge the contributions of one another in accordance with standard academic practice regarding authorship of scientific publication.

Each Party agrees to comply, with respect to the listing of Clinical Trials or the publication of Clinical Trial information and results with respect to Licensed Products and to the extent applicable to its activities conducted under this Agreement, with any Applicable Law or applicable court order, stipulations, consent agreements and settlements entered into by such Party; provided that any listings or publications made pursuant to this Section 10.3 (Publications and Presentations). [***] will provide such assistance as [***] may reasonably require to obtain any consent or permission that may be required in order to publish data that originates from [***].

11 REPRESENTATIONS, WARRANTIES, AND COVENANTS

11.1 Mutual Representations and Warranties

As of the Execution Date, Biotheus and BioNTech each hereby represents and warrants to the other as follows:

(a) **Organization**

It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

(b) **Authorization**

The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and will not violate (a) such Party's certificate of incorporation or bylaws (or equivalent charter or organizational documents), (b) any agreement, instrument or contractual obligation to which such Party is bound, (c) any requirement of any Applicable Law or regulations or court or administrative under, or (d) any order, writ, judgment, injunction, decree, determination, or award of any court or Governmental Authority presently in effect applicable to such Party.

(c) **No Inconsistent Obligation**

It is not under any obligation, contractual, or otherwise, to any Person that conflicts with or is inconsistent in any respect with the terms of this Agreement or that will impede the diligent and complete fulfillment of its obligations hereunder.

(d) **No Litigation**

There is no action or proceeding pending or, to the knowledge of such Party, threatened that could reasonably be expected to impair or delay the ability of such Party to perform its obligations under this Agreement.

(e) **Government Authorizations**

All consents, approvals, and authorizations from all Governmental Authorities or other Third Parties required to be obtained by such Party in connection with this Agreement, including the grant of any licenses, have been obtained.

(f) **Debarment**

Neither such Party, nor any Affiliate of such Party, has been debarred by any Regulatory Authority, including under the Generic Drug Enforcement Act of 1992 (21 U.S.C. §301 et seq.), and the Drug Administration Law and the Human Genetic Resource Regulations in China, is under investigation for debarment action by any Regulatory Authority, has been disqualified as an investigator pursuant to 21 C.F.R. §312.70, and the Drug Administration Law and the Human Genetic Resource Regulations in China, has a disqualification hearing pending or is currently employing or using any Person that has been so debarred or disqualified by any Regulatory Authority to perform any of such Party's obligations under this Agreement.

11.2 **Additional Representations of Biotheus as of the Execution Date**

As of the Execution Date, and as of the PM8003 Option Exercise Date and the Preclinical Multispecific Option Exercise Date (as applicable), Biotheus further represents and warrants to BioNTech, that, except as set forth in Schedule 2 (Exceptions to Representations and

Warranties) (which may be updated by Biotheus with respect to the PM8003 Licensed Compound and/or PM8003 Licensed Products or Preclinical Multispecific Licensed Compound and/or Preclinical Multispecific Licensed Products (as applicable) only upon written notice by Biotheus to BioNTech at any time after the Execution Date and prior to the PM8003 Option Exercise Date or Preclinical Multispecific Option Exercise Date (as applicable), provided that any such updates may relate solely to matters that have arisen in the period following the Execution Date):

(a) **Licensed Patent Rights**

Schedule 3 sets forth a complete and accurate list of all Licensed Patent Rights in existence as at the Execution Date, all of which are owned or Controlled by Biotheus. Biotheus and its Affiliates have not committed, and to the knowledge of Biotheus no Third Party has committed, any act, or omitted to commit any act, that may cause the Licensed Patent Rights to expire prematurely or be declared invalid or unenforceable, and all application, registration, maintenance and renewal fees in respect of the Licensed Patent Rights have been paid and all necessary documents and certificates have been filed with the relevant agencies for the purpose of maintaining the Licensed Patent Rights set forth in Schedule 3.

(b) **Licensed Know-How and Trade Secrets**

Biotheus and its Affiliates have maintained in confidence and have not disclosed to any Third Party the Licensed Know-How, except under terms which require any such Third Party to keep the Licensed Know-How confidential.

(c) **Biotheus Inventions and Assignments**

With respect to any Licensed IP owned by Biotheus, (a) Biotheus and its Affiliates have obtained from all individuals who contributed to the conception or reduction to practice thereof, effective assignments of all ownership rights of such individuals in such Licensed IP, either pursuant to written agreement or by operation of law, (b) all of its employees, officers, and consultants have executed agreements or have existing obligations under Applicable Law requiring assignment to Biotheus or its Affiliates, as

applicable, of all inventions made prior to the Execution Date, and no officer or employee of Biotheus or its Affiliates is subject to any agreement with any other Third Party that requires such officer or employee to assign any interest in any Licensed IP to any Third Party, and (c) the conception, development, and reduction to practice of any such Licensed IP has not constituted or involved the misappropriation of any trade secrets or other rights or property of any Person.

(d) **License to BioNTech**

Biotheus has the right and authority to: (a) grant to BioNTech and its Affiliates the licenses under the Licensed IP that Biotheus grants to BioNTech in accordance with the terms and conditions of this Agreement; and (b) use, disclose and Exploit, and to enable BioNTech and its Affiliates to use, disclose and Exploit the Licensed IP in accordance with the terms and conditions of this Agreement.

(e) **No Biotheus Infringement**

There is no pending action or proceeding alleging that the use of the Licensed IP infringes, misappropriates or otherwise violates any Intellectual Property Rights of any Third Party, and there is no pending action or proceeding alleging that the use of the Licensed IP as contemplated under this Agreement infringes, misappropriates, or otherwise violates any Intellectual Property Rights of any Third Party.

(f) **No Third Party Infringement**

To the knowledge of Biotheus, no Patent Right or trade secret right owned or controlled by a Third Party will be infringed or misappropriated by the performance of the Global CDP Activities or Joint CDP Activities or the Exploitation of the Licensed Products, in each case, in accordance with this Agreement, nor has Biotheus or its Affiliates received in writing any notice alleging such infringement or misappropriation.

(g) **No Claims**

There are no claims, judgments, or settlements against or amounts with respect thereto owed by Biotheus or any of its Affiliates relating to the Licensed Product or Licensed IP.

(h) **Biotheus In-Licenses**

As of the Execution Date, there are no agreements or other arrangements to which Biotheus or its Affiliates are a party that could be a Biotheus In-License except the [***] License. Biotheus is not a party to any agreement or arrangement containing terms that conflict with or would prevent Biotheus from performing its obligations and granting the rights set out in this Agreement.

(i) **[***] IP**

No background intellectual property of [***] has been used in the development of the Licensed IP or Licensed Products. Biotheus has paid all outstanding fees to its CMOs including [***] pursuant to the [***] between Biotheus and [***].

(j) **No Government Funding**

The preclinical and clinical development of the Licensed Products was not carried out and all inventions claimed or Covered by the Licensed IP were not conceived, discovered, developed, or otherwise made in connection with any research activities funded, in whole or in part, by a government or any agency thereof or public institution such as the Chinese Academy of Sciences that would entitle any government or governmental agency or public institution to claim any ownership right or interest in the Licensed Products or the Licensed IP.

(k) **Compliance with Applicable Law**

The pre-clinical and clinical development by or on behalf of Biotheus of Licensed Products has been carried out in accordance with Applicable Law and there are no pending or concluded inquiries, investigations, or proceedings by any Regulatory

Authority or Governmental Authority or public institution in relation to Licensed Products.

(l) **Clinical Trials**

Biotheus and its Affiliates are not aware of any adverse event or other safety issue in relation to a Licensed Product arising from the conduct of the Clinical Trials that have been conducted or are in the process of being conducted in relation to Licensed Products as at the Execution Date. Biotheus has disclosed to BioNTech all data and information arising from such trials. Biotheus and its Affiliates have not received any notice of any actual or potential claim, proceedings or other dispute arising out of or relating to such Clinical Trials.

(m) **Accuracy of information**

All information provided by Biotheus to BioNTech in writing for due diligence purposes in relation to and in contemplation of this Agreement is accurate in all material respects. Without limiting the foregoing, Biotheus has disclosed to BioNTech and made available to BioNTech for review all material data, and all other material information relating to the Licensed IP and to Licensed Products that is in the possession and Control of Biotheus or its Affiliates.

(n) **Financial Position**

Biotheus and its Affiliates (a) are solvent, (b) have sufficient financial resources to conduct its business in the ordinary course, meet all of its debts and financial obligations, and have no reasonable basis on which to expect that its operations may be impaired by financial instability or insolvency, and (c) shall take no actions during the Term of this Agreement that would materially impair its financial ability to meet its obligations hereunder, or otherwise materially impairing its ability to meet its debts and financial obligations in the ordinary course.

(o) **Export Restrictions**

The are no Applicable Laws (including pursuant to the Export Control Law of the People's Republic of China, Administrative Measures for the Import and Export Permits of Dual-use Items and Technology, Administrative Regulations of the People's Republic of China on Technology Import and Export (Revised in 2020) and the Human Genetic Resources regulation in China) that will materially restrict Biotheus' ability to comply with the terms of this Agreement including with respect to the transfer to BioNTech of the Licensed IP and any materials that are to be supplied by Biotheus to BioNTech. And, to the extent required by Applicable Laws, Biotheus has obtained or will obtain at the time of transfer all clearances, authorizations and/or consents required for transferring all Licensed IP and materials to BioNTech under the applicable technology and data reporting control laws in the Territory, including a filing in the Retained Territory under the Administrative Measures for the Registration of Technology Import and Export Contracts, if applicable.

11.3 Compliance Covenants

Each of BioNTech and Biotheus covenant to the other as follows:

(a) **Compliance with Law**

It will, and will ensure that its Affiliates will, comply with all Applicable Law in connection with the performance of its and its Affiliates' activities under this Agreement, including Applicable Data Protection Law. In addition Biotheus will implement and maintain an internal control and compliance management program designed to effectively prevent and detect wrongdoing by employees and the management of Biotheus that is suitable for a Chinese biotech company of comparable size.

(b) **No Inconsistent Obligations**

It will not, and will ensure that its Affiliates will not, take any action or enter into any agreement with any Third Party that conflicts with or in any way diminishes the rights granted to the other Party under this Agreement.

(c) **No Bribery**

It will not undertake any activities which will result in a violation of any Applicable Laws, regulations, and applicable industry and professional codes, including but not limited to applicable local and extraterritorial anti-bribery, anti-corruption and anti-money laundering laws (collectively "**Prohibited Conduct**") in connection with the performance of any activities under this Agreement. In particular, each Party agrees that during the course of the performance of activities under this Agreement, it (i) shall not make any offer, payment, or promise to pay money or provide anything of value to a Government Official (as defined below) or any other individual and/or legal entity whether directly or indirectly, for the purpose of improperly influencing any act and/or decision of, and/or for securing any improper advantage; (ii) shall not accept, receive, agree to accept and/or receive a payment and/or anything of value from any individual for undue favorable treatment in obtaining, retaining, and/or directing business for, and/or to obtain any undue special concession on behalf of the other Party; (iii) shall not facilitate any payments to any Government Official to expedite a routine government action and/or other official act. All transactions and expenses incurred by a Party on behalf of the other Party shall be accurately recorded and maintained in the incurring Party's books and records in a timely manner and in reasonable detail in accordance with generally accepted accounting principles. False, misleading, incomplete, duplicated, inaccurate or artificial entries in a Party's books and records are strictly prohibited. Each Party agrees that if it becomes aware or has reason to suspect that any person or legal entity acting on a Party's behalf has engaged in any Prohibited Conduct related to the Agreement, then the Party will immediately report such knowledge or suspicion to the other Party and if [***] is the notifying Party it shall notify [***] via the following email address: [***]. Each Party agrees to provide reasonable cooperation in any investigation that may be conducted by or on behalf of the other Party related to business in connection with the Agreement. Upon notice of an intended investigation, the notified Party will provide, in a reasonable time, to the other Party or to a Third Party engaged by the other Party: (a) access to the relevant persons; and/or (b) access to relevant documents and data (e.g. invoices and requests for expense reimbursement, supporting receipts and substantiation, and original entry records for charges and payments). Each Party acknowledges that the obligations under this Section apply to all its employees and sub-contractors who act

for or on behalf of such Party to perform activities under this Agreement. Each Party will bind sub-contractors who act for or on its behalf under the Agreement by respective contractual clauses encompassing all material provisions of this Section.

(d) **Export Control**

Neither it nor its Affiliates will export, transfer, or sell any Licensed Product to any country or territory except in compliance with Applicable Law.

(e) **Debarment**

It will not engage, in any capacity in connection with this Agreement or any ancillary agreements, any officer, employee, contractor, consultant, agent, representative, or other person who has been debarred by any Regulatory Authority, including under the Generic Drug Enforcement Act of 1992 (21 U.S.C. §301 et seq.), is under investigation for debarment action by any Regulatory Authority, has been disqualified as an investigator pursuant to 21 C.F.R. §312.70, has a disqualification hearing pending or is currently employing or using any Person that has been so debarred or disqualified by any Regulatory Authority to perform any of such Party's obligations under this Agreement. Each Party will inform the other Party in writing promptly if it or any person engaged by it or any of its Affiliates who is performing any obligations under this Agreement or any ancillary agreements is debarred or excluded, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to each Party's knowledge, is threatened, pursuant to which a Party, any of its Affiliates or any such person performing obligations hereunder or thereunder may become debarred or excluded.

(f) **Biotheus Covenants**

Biotheus will not enter into any agreement with respect to or assign, transfer, license, convey or otherwise encumber its right, title or interest in or to (i) the Licensed IP (including by granting any covenant not to sue with respect thereto) or (ii) any intellectual property or proprietary right that would be Licensed IP, but for such assignment, transfer, license, conveyance or encumbrance, in each case of (i) and

(ii), that is inconsistent with the rights and licenses granted to BioNTech under this Agreement. Biotheus shall, and shall ensure that its Affiliates shall, maintain the Biotheus In-Licenses in full force and effect in accordance with their terms and conditions and without any amendment that conflicts with the rights granted to BioNTech under this Agreement or may otherwise adversely affect the rights granted to BioNTech under this Agreement, except with BioNTech's prior written consent. In the event that Biotheus or any of its Affiliates or sublicensees receives notice of an alleged breach or default of a Biotheus In-License where the Third Party licensor or counterparty to such Biotheus In-License may terminate such agreement or otherwise take action that would diminish the scope or exclusivity of the licenses granted to BioNTech herein, then Biotheus shall promptly, but in no event less than [***] Business Days thereafter, notify BioNTech of such alleged breach or default in writing and hereby grants to BioNTech the right (but not the obligation) to: (i) cure such undisputed breach or default that has been confirmed by Biotheus and (ii) offset any reasonable costs or expenses incurred in connection therewith, including payments made to the Third Party licensor by BioNTech on behalf of Biotheus to cure said confirmed breach or default by Biotheus against any payments due or that may become due from BioNTech to Biotheus under this Agreement. Biotheus shall keep BioNTech promptly informed of any Know-How or Patent Rights related to Licensed Products created or filed by the respective licensors under the Biotheus In-Licenses including any such Patent Rights and Know-How in relation to which Biotheus has an option to negotiate the terms of a license from the applicable licensor pursuant to a Biotheus In-License. This provision will not restrict or eliminate any of BioNTech's remedies under this Agreement or otherwise available for BioNTech under any law or equity.

If Biotheus has an obligation under this Agreement to provide data, materials and information to BioNTech or to grant licenses to intellectual property rights, Biotheus will at its cost obtain any approvals, permissions, consents, or other documentation that are necessary to have for exporting such data, information and materials from China to BioNTech or to grant licenses to such intellectual property rights, (the "**Governmental Approval**"). If, prior to the date on which Manufacturing Technology Transfer is successfully completed for PM8002 Licensed Product pursuant to Section 7.2 (Manufacturing Technology Transfer for PM8002 Licensed Products), Biotheus

does not obtain such Governmental Approvals required under Applicable Law in China within a reasonable period of time with the result that BioNTech is not able to receive the material benefit of this Agreement in respect of PM8002 Licensed Product, BioNTech will be entitled to terminate this Agreement in respect of PM8002 Licensed Product and obtain a refund of the Upfront Payment that has been made by BioNTech to Biotheus under this Agreement.

In addition, where Biotheus has an obligation under this Agreement to provide reports, information, documentation and the like they shall be accompanied with an English translation if the original documents are not in English.

Biotheus will not obtain any funding from a Governmental Authority that could restrict Biotheus' ability to comply with the terms of this Agreement including but not limited to the provisions of Section 3.1 (License Grants to BioNTech).

Within [***] prior to successful completion of the Manufacturing Technology Transfer for PM8002 Licensed Product pursuant to Section 7.2 (Manufacturing Technology Transfer for PM8002 Licensed Products), Biotheus will provide to BioNTech a copy of Biotheus' unaudited financial statements for the previous [***] period. Any such statements and accounts shall be the Confidential Information of Biotheus and shall only be used by BioNTech for the purposes of monitoring Biotheus' financial position. The foregoing information furnishing obligations shall (i) suspend once Biotheus (or its applicable Affiliate) files for an initial public offering to be listed on an international or national stock exchange that requires public disclosure of financial statements, as long as the financial statements of Biotheus (or its applicable Affiliate) contained in such filing remains no more than [***] old and (ii) terminate upon closing of Biotheus' (or its applicable Affiliate's) initial public offering on an international or national stock exchange that requires public disclosure of financial statements.

Notwithstanding the foregoing Biotheus will give written notice to BioNTech immediately if at any time Biotheus becomes aware of its inability to carry on as a going concern.

Biotheus agrees, on behalf of itself and its Affiliates, not to take any action or fail to take any action in the period between the Execution Date and the Effective Date that would cause or be reasonably likely to cause any of the representations and warranties by Biotheus set forth in Sections 11.1 (Mutual Representations, Warranties and Covenants) or 11.2 (Additional Representations of Biotheus as of the Execution Date) to be untrue in any material respect if made as of the Effective Date.

(g) **Tax Evasion**

Neither Party, nor any of its Affiliates shall commit a tax evasion facilitation offence under Part 3 of the UK Criminal Finances Act 2017 in connection with or otherwise attributable to this Agreement or the transactions contemplated hereby. Each Party shall promptly report to the other Party any apparent breach of this Section 11.3(g) (Tax Evasion) and shall (a) answer, in reasonable detail, any written or oral inquiry from the other Party related to its and its Affiliates' compliance with this Section 11.3(g) (Tax Evasion), (b) facilitate the interview of employees of such Party by the other Party (or any agent of such Party) at any reasonable time specified by the inquiring Party related to such Party's compliance with this Section 11.3(g) (Tax Evasion), and (c) co-operate with the inquiring Party or any Governmental Authority in relation to any investigation relating to the matters referred to in this Section 11.3(g) (Tax Evasion), in all cases, as reasonably required to enable that other Party to comply with its undertaking in this Section 11.3(g) (Tax Evasion).

12 INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE

12.1 Indemnification of Biotheus by BioNTech

Subject to Section 12.3 (Conditions to Indemnification), BioNTech will defend, indemnify, and hold harmless Biotheus and its Affiliates, and their respective employees, officers, and directors ("**Biotheus Indemnitees**") from and against any and all liability, damage, loss, cost or expense of any nature (including reasonable attorney's fees and litigation expenses) ("**Losses**") incurred or imposed upon the Biotheus Indemnitees or any one of them in connection with any claims, suits, actions, demands, proceedings, causes of action or judgments resulting from a Third Party claim arising out of or relating to: (a) the conduct of

activities under the Global CDP by a BioNTech Indemnitee; (b) the Development, Manufacture or Commercialization of any Licensed Product by or on behalf of any BioNTech Indemnitee; (c) the breach by any BioNTech Indemnitee of any term of this Agreement; or (d) the negligence or wilful misconduct of any BioNTech Indemnitee except, in each case ((a) through (d)), to the extent that any such claim results or arises from a matter for which Biotheus is obligated to indemnify BioNTech under Section 12.2 (Indemnification of BioNTech by Biotheus).

12.2 Indemnification of BioNTech by Biotheus

Subject to Section 12.3 (Conditions to Indemnification), Biotheus will defend, indemnify, and hold harmless BioNTech and its Affiliates, Sublicensees, and licensees, and their respective employees, officers and directors ("**BioNTech Indemnitees**") from and against any and all Losses incurred or imposed upon the BioNTech Indemnitees or any one of them in connection with any claims, suits, actions, demands, proceedings, causes of action, or judgments resulting from a Third Party claim arising out of or relating to (a) the conduct of activities under the Global CDP or the Joint CDP by a Biotheus Indemnitee; (b) the Development, Manufacture or Commercialization of any Licensed Product by or on behalf of any Biotheus Indemnitee, (c) the breach by any Biotheus Indemnitee of any term of this Agreement; or (d) the negligence or wilful misconduct of any Biotheus Indemnitee except, in each case ((a) through (d)), to the extent that any such claim results or arises from a matter for which BioNTech is obligated to indemnify Biotheus under Section 12.1 (Indemnification of Biotheus by BioNTech).

12.3 Conditions to Indemnification

Any Person seeking indemnification (the "**Indemnitee**") under this Section 12 (Indemnification; Limitation Of Liability; Insurance) will give prompt written notice of the indemnity claim to the indemnifying Party and promptly provide a copy to the indemnifying Party of any complaint, summons, or other written or verbal notice that the Indemnitee receives in connection with any such claim. An Indemnitee's failure to deliver written notice will relieve the indemnifying Party of liability to the Indemnitee under this Section 12 (Indemnification; Limitation of Liability; Insurance) only to the extent such delay is prejudicial to the indemnifying Party's ability to defend or settle such claim. The indemnifying Party will

have the right to assume and control the defense of the indemnification claim at its own expense with counsel selected by the indemnifying Party and reasonably acceptable to the Indemnitee; *provided, however*, that an Indemnitee will have the right to retain its own counsel, with the fees and expenses to be paid by the indemnifying Party, if representation of such Indemnitee by the counsel retained by the indemnifying Party would be inappropriate due to actual or potential differing interests between the Indemnitee and any other party represented by such counsel in such proceedings. The indemnifying Party will act reasonably and in good faith with respect to all matters relating to such claim. If the indemnifying Party does not assume the defense of the indemnification claim as described in this Section 12.3 (Conditions to Indemnification), then the Indemnitee may defend the indemnification claim but will have no obligation to do so. The Indemnitee will not settle or compromise the indemnification claim without the prior written consent of the indemnifying Party, and the indemnifying Party will not settle or compromise the indemnification claim in any manner which would have an adverse effect on the Indemnitee's interests (including any rights under this Agreement or the scope, validity, or enforceability of any Patent Rights, Confidential Information, or other rights licensed to BioNTech by Biotheus hereunder), without the prior written consent of the Indemnitee, which consent, in each case (by the indemnifying Party or the Indemnitee, as the case may be), will not be unreasonably withheld, conditioned, or delayed. The Indemnitee will reasonably cooperate with the indemnifying Party at the indemnifying Party's expense and will make available to the indemnifying Party all pertinent information under the control of the Indemnitee, which information will be subject to 10.1 (Confidentiality). The indemnifying Party will not be liable for any settlement or other disposition of the claims by the Indemnitee if such settlement is reached without the written consent of the indemnifying Party pursuant to this Section 12.3 (Conditions to Indemnification).

12.4 **Limited Liability**

NEITHER OF THE PARTIES WILL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, INDIRECT, CONSEQUENTIAL, OR PUNITIVE DAMAGES OR DAMAGES FOR LOSS OF PROFIT OR LOST OPPORTUNITY IN CONNECTION WITH THIS AGREEMENT, ITS PERFORMANCE OR LACK OF PERFORMANCE HEREUNDER, OR ANY LICENSE GRANTED HEREUNDER, EXCEPT TO THE EXTENT RESULTING FROM (A) A PARTY'S WILLFUL MISCONDUCT OR

NEGLIGENCE UNDER THIS AGREEMENT, (B) A BREACH OF THE OBLIGATIONS OF A PARTY UNDER 10.1 (CONFIDENTIAL INFORMATION), OR (C) AMOUNTS REQUIRED TO BE PAID AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER ARTICLE 12 (INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE). No provision of this Agreement shall limit a Party's liability for death or personal injury caused by its negligence or for fraud or any other liability that cannot be excluded under Applicable Law.

12.5 Insurance Obligations

Each Party will maintain during the Term and for a period of at least [***] years after the last commercial sale of any Licensed Product pursuant to this Agreement, at its cost, reasonable insurance (including but not limited to product liability insurance) with a reputable solvent insurer against liability and other risks associated with its activities contemplated by this Agreement in an amount appropriate for its business and products of the type that are the subject of this Agreement, and for its obligations under this Agreement. Without limiting the preceding sentence, where a Party is carrying out Clinical Trials pursuant to this Agreement, such Party will maintain, at its cost, specific Clinical Trials insurance that is appropriate for such activities in the applicable territory, in accordance with applicable law. For clarity, if Biotheus conducts the Joint Trials on BioNTech's behalf pursuant to the terms of this Agreement, the costs of Clinical Trials insurance for any such Joint Trials shall [***] and be solely borne by [***]. Each Party will furnish to the other Party evidence of all such insurance upon request. Notwithstanding the foregoing, such obligation may be satisfied by a program of self-insurance.

13 TERM AND TERMINATION

13.1 Term

This Agreement will commence on the Effective Date (except for Section 10.1 (Confidential Information), Article 11 (Representations, Warranties and Covenants) and Section 14.16 (HSR) which shall commence on the Execution Date) and, unless otherwise terminated pursuant to Section 13.2 (Termination), will continue on a Licensed Product-by-Licensed Product basis until the earlier of (a) the expiration of all applicable payment obligations with respect to each such Licensed Product on a country-by-country-basis in the Territory; (b) in

respect of PM8003 Licensed Products, in the event that BioNTech does not exercise the PM8003 Option, until the end of the PM8003 Option Period (including any extensions thereto); or (c) in respect of Preclinical Multispecific Licensed Products, in the event that BioNTech does not exercise the Preclinical Multispecific Option, until the end of the Preclinical Multispecific Option Period (including any extensions thereto) for each such Preclinical Multispecific Licensed Product (the "**Term**"). On a Licensed Product-by-Licensed Product and country-by-country basis (and, in the case of PM8003 Licensed Products and/or Preclinical Multispecific Licensed Products (as applicable), subject to BioNTech's exercise of the PM8003 Option or Preclinical Multispecific Option (as applicable)), effective upon the expiration of the Royalty Term for such Licensed Product in such country (but not upon any earlier termination of this Agreement for any reason), the licenses granted to BioNTech will each become exclusive, fully paid-up, royalty-free, irrevocable, and perpetual in such country with respect to such Licensed Product.

13.2 Termination

This Agreement may be terminated as follows:

(a) **Termination for Convenience by BioNTech or Biotheus**

BioNTech may, at any time, terminate this Agreement as a whole or on a Licensed Product-by-Licensed Product basis at will, in its sole discretion: (i) on [***] (or [***] days where BioNTech terminates the Agreement pursuant to Article 8 (Financial Terms) due to the Qualification Date not being achieved) prior written notice to Biotheus where the notice for termination of a Licensed Product is provided before the completion of a Registrational Clinical Trial in respect of such Licensed Product; and (ii) on [***] prior written notice to Biotheus where the notice for termination of a Licensed Product is provided after the completion of a Registrational Clinical Trial in respect of such Licensed Product; provided that if the termination of this Agreement by BioNTech pursuant to this Section 13.2(a) (Termination for Convenience by BioNTech or Biotheus) requires a notice period of [***] under the foregoing clause (ii) and a milestone is achieved by or on behalf of BioNTech pursuant to Section 8.3 (Development and Approval Milestone Payments for Licensed Products) during said notice period of [***] days, BioNTech shall have no obligation to pay to Biotheus the

applicable milestone payment corresponding to such achieved milestone. If BioNTech does not complete the audit and, as applicable, qualification contemplated in Article 8 (Financial Terms) and notify Biotheus of the results thereof in writing on or before [***], Biotheus shall be entitled to terminate this Agreement as a whole on [***] days prior written notice to BioNTech.

(b) **Termination for Breach**

If a Party commits a material breach of this Agreement, then the other Party may terminate this Agreement with respect to the applicable Licensed Product that is the subject of such material breach, unless such material breach is cured within (a) the [***] day period after receipt of written notice from the non-breaching Party with respect to any breach of any payment obligation under this Agreement, or (b) the [***] period after receipt of written notice from the non-breaching Party with respect to any other material breach under this Agreement, provided that if the alleged breaching Party disputes in good faith the existence or materiality of any such material breach specified in the notice provided by the other Party, and the alleged breaching Party provides notice of such dispute within such [***] period, then the Party alleging such material breach will not have the right to terminate this Agreement unless and until such material breach has been confirmed through the dispute resolution process in accordance with Section 14.1 (Dispute Resolution).

(c) [***]

(d) **Termination for Bankruptcy**

This Agreement may be terminated in its entirety by a Party (the "**Non-Bankrupt Party**") by providing written notice of termination to the other Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party including in each case occurrence of the applicable or similar corresponding event under the Enterprise Bankruptcy Law of the People's Republic of China, as may be modified (the "**Bankrupt Party**"); provided, however, that in the event of any involuntary bankruptcy or receivership proceeding such right to terminate

will only become effective if the Bankrupt Party consents to the involuntary bankruptcy or receivership or such proceeding is not dismissed within [***] days after the filing of such bankruptcy or receivership.

13.3 **Effects of Termination**

In the event of any termination of this Agreement, effective as of the effective date of termination, the following provisions will apply with respect to the terminated Licensed Products ("**Terminated Products**"), as applicable:

- (a) [***]
- (b) [***]
- (c) [***]
- (d) **Ongoing Clinical Trials**

Notwithstanding any other provision in this Section 13.3 (Effects of Termination), if there are any Clinical Trials or patient treatments using a Licensed Product being conducted as of the effective date of termination, BioNTech shall be entitled to continue Developing or Exploiting Licensed Products to the extent and for the period necessary to effect an orderly transfer or wind down of such Clinical Trials or patient treatments in a timely manner and in accordance with all Applicable Laws. In addition, as promptly as practicable after such termination, BioNTech shall: (i) transfer or assign, or cause to be transferred or assigned, to Biotheus or its designee (or to the extent not so assignable, take all reasonable actions to make available to Biotheus or its designee the benefits of) all Regulatory Filings, Regulatory Documentation and Regulatory Authorization to the extent they solely relate to such Licensed Products in the Territory, whether held in the name of BioNTech or its Affiliate, or (ii) provide Biotheus with a right of reference with respect to any such Regulatory Filings and Regulatory Documentation at no cost to Biotheus; and (iii) take such other actions and execute such other instruments, assignments and documents as may be reasonably necessary to effect, evidence, register and record the transfer, assignment or other conveyance of rights under this Section 13.3(d) (Ongoing Clinical Trials) to Biotheus,

in each case at the cost of BioNTech if this Agreement is terminated by BioNTech pursuant to Section 13.2(a) (Termination for Convenience by BioNTech or Biotheus) or by Biotheus pursuant to Section 13.2(b) (Termination for Breach) or 13.2(d) (Termination for Bankruptcy), or at the cost of Biotheus if this Agreement is terminated for any other reason whatsoever.

(e) **Accrued Rights and Obligations**

Neither expiration nor any termination of this Agreement for whatsoever reason shall relieve either Party of any obligation or liability accruing prior to such expiration or termination, nor shall expiration or any termination of this Agreement for whatsoever reason preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement. Such obligations and rights shall survive termination and expiration of this Agreement. For clarity, (i) except in the circumstances set out in Section 13.2(a)(ii), if any milestone event is achieved during the applicable termination notice period, then the corresponding milestone payment is accrued and BioNTech shall remain responsible for the payment of such milestone payment even if the due date of such milestone payment may come after the effective date of the termination; and (ii) BioNTech shall make payment to Biotheus for all applicable Eligible Development Costs incurred up to the effective date of termination of this Agreement and not yet paid for (if any) (including all non-cancellable documented commitments incurred consistent with the Joint CDP prior to the date of notice of termination of this Agreement).

(f) **Other Effects**

[***]

13.4 **Confidential Information and Materials**

Upon termination of this Agreement for any reason, the Receiving Party will: (i) return to the other Party any Materials provided to it in connection with this Agreement, within [***] days of termination except to the extent necessary for the Receiving Party to exercise any other license or right that survives such termination of this Agreement, provided that the Receiving

Party's use of such Materials will continue to be subject to Section 3.4(c) (Knowledge and Technology Transfer); and (ii) destroy all written, electronic, or other materials containing Confidential Information of the Disclosing Party provided to it by the Disclosing Party in connection with this Agreement, including all copies thereof, within [***] days of such termination and provide certification of such destruction to the Disclosing Party; *provided*, that (a) the Receiving Party may retain one copy in its archives solely for the purpose of monitoring its ongoing confidentiality obligations hereunder, and (b) the Receiving Party will not be obligated to destroy such materials containing Confidential Information of the Disclosing Party that are necessary for the Receiving Party to exercise any other license or right of the Receiving Party that survives such termination of this Agreement; PROVIDED THAT the Receiving Party's use of such Confidential Information of the Disclosing Party will continue to be subject to the requirements and restrictions set forth in Section 10.1 (Confidential Information).

13.5 **Surviving Provisions**

Subject to the other terms and conditions regarding the termination and survival of obligations under this Agreement in the event of expiration or termination of this Agreement, upon expiration or termination of this Agreement, all provisions of this Agreement will cease to have any effect, except that the following provisions will survive any such expiration or termination for any reason for the period of time specified therein, or if not specified, then they will survive indefinitely: Article 1 (Definitions); Section 8.12 (Records and Audits); Section 9.1(a) (Ownership), Section 10.1 (Confidential Information); Article 12 (Indemnification, Limitation of Liability, Insurance), Article 13 (Term and Termination) and Article 14 (Miscellaneous). Termination of this Agreement will not relieve either Party of any liability that accrued hereunder prior to the effective date of such termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement. The remedies provided in this Article 13 (Term and Termination) are not exclusive of any other remedies a Party may have in law or equity.

14 MISCELLANEOUS

14.1 Dispute Resolution

(a) Escalation

In the event of any dispute, claim, controversy, or cause of action asserted by a Party against the other Party or by the Biotheus Indemnitees against BioNTech or by the BioNTech Indemnitees against Biotheus arising out of or related to this Agreement or performance of this Agreement (other than matters within the purview of the JSC, which will be resolved as set forth in Section 4.5 (Decision-Making)) (a "**Claim**"), including any alleged breach of this Agreement or claim for indemnification pursuant to Article 12 (Indemnification; Limitation of Liability; Insurance), such Party may, by written notice to the other Party, refer such matter to the Parties' respective officers designated below for attempted resolution (each, an "**Executive Officer**"):

For BioNTech: CEO (or other senior executive designated by BioNTech for such purpose)

For Biotheus: CEO (or other senior executive designated by Biotheus for such purpose)

(b) Arbitration

Except as otherwise expressly set forth in this Agreement, if such Executive Officers do not resolve the dispute within [***] days after receipt of such request, then any dispute arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination, shall be referred to and finally resolved by binding arbitration administered by the Hong Kong International Arbitration Centre ("**HKIAC**") (or any successor entity thereto) pursuant to the United Nations Commission on International Trade Law ("**UNCITRAL**") Arbitration Rules in force when the notice of arbitration is submitted, as modified by the HKIAC Procedures for the Administration of Arbitration under the UNCITRAL Arbitration Rules. The number of arbitrators shall be [***]. If the issues in dispute involve scientific, technical or

commercial matters, the arbitrators chosen hereunder shall engage experts having educational training or industry experience sufficient to demonstrate a reasonable level of relevant scientific, medical and industry knowledge, as necessary to resolve the dispute. The seat, or legal place, of arbitration shall be Hong Kong. The language to be used in the arbitral proceedings shall be English. The governing law of the Agreement shall be the substantive law of England and Wales as set out in Section 14.4 (Governing Law).

14.2 Designation of Affiliates

Each Party may discharge any obligations and exercise any rights under this Agreement through delegation of its obligations or rights to any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement will be a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

14.3 Injunctive Relief

Notwithstanding anything to the contrary set forth in this Agreement, the Parties each stipulate and agree that (a) the other Party's Confidential Information includes highly sensitive trade secret information, (b) a violation of the licenses granted to BioNTech under Section 3.1 (License Grants to BioNTech) or a breach of 10.1 (Confidential Information) by a Party with respect to such information may cause irrevocable harm for which monetary damages would not provide a sufficient remedy, and (c) in such case of a breach of Section 3.1 (License Grants to BioNTech) or 10.1 (Confidential Information), the non-breaching Party will be entitled to equitable relief (including temporary or permanent restraining orders, specific performance or other injunctive relief) from any court of competent jurisdiction. In addition, and notwithstanding anything to the contrary set forth in this Agreement, in the event of any other actual or threatened breach hereunder, the aggrieved Party may seek equitable relief (including temporary or permanent restraining orders, specific performance or other injunctive relief) from any court of competent jurisdiction without first submitting to the dispute resolution procedures set forth in Section 14.1 (Dispute Resolution).

14.4 **Governing Law**

This Agreement and any issues, disputes or claims arising out of or in connection with it (whether contractual or non-contractual in nature such as claims in tort, from breach of statute or regulation or otherwise) will be governed by and construed in accordance with the laws of England and Wales without taking into consideration any choice of law principles that would lead to the application of the laws of another jurisdiction.

14.5 **Cumulative Remedies**

The rights and remedies of the Parties under this Agreement are cumulative and not exclusive and, accordingly, are in addition to and not in lieu of any other rights and remedies of the Parties at law or in equity.

14.6 **Notices**

Any notice or report required or permitted to be given or made under this Agreement by either Party to the other will be in writing and delivered to the other Party at its address indicated below or to such other address as the addressee will have theretofore furnished in writing to the addressor by hand, courier or by registered or certified airmail (postage prepaid), in writing, by registered or certified airmail (postage prepaid):

(a) **If to BioNTech:** BioNTech SE

An der Goldgrube 12,
55131 Mainz, Germany
Attention: [***]

Email: [***]

(b) **If to Biotheus:** Biotheus Inc.

12A, Building 4, No. 1 Keji 7th Road,

Tangjiawan Town, Zhuhai,

Guangdong, China 519080

Attention: [***]

Email: [***]

Copy to (which copy will not constitute notice):

Goodwin Procter LLP

The New York Times Building

620 Eighth Avenue

New York, NY 10018 USA

Attention: [***]

Email: [***]

All notices will be deemed effective: (a) if by courier, on the Business Day of delivery as evidenced by the courier's receipt (or if delivered or sent on a non-Business Day, then on the next Business Day); or (b) if sent by registered or certified airmail, on the Business Day of receipt as evidenced on the return receipt.

14.7 **Amendment; Waiver**

This Agreement may be amended, modified, superseded or cancelled only by a written agreement between the Parties, and any of the terms of this Agreement may be waived only by a written instrument executed by each Party or, in the case of waiver, by the Party or Parties waiving compliance. Except as otherwise provided in this Agreement, the Schedules to this Agreement may be amended, modified, superseded or cancelled only by a written agreement between the Parties. The delay or failure of either Party at any time or times to require performance of any provisions will in no manner affect the rights at a later time to enforce the same. No waiver by either Party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, will be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.

14.8 Cyber Security Requirements

- (a) In performing its obligations and exercising its rights under this Agreement, each Party warrants and represents to the other Party that it will maintain adequate administrative, technical, and physical measures, controls, tools, systems, policies and procedures in accordance with good cyber security industry practice and all Applicable Laws.
- (b) Each Party will notify the other Party, in writing, of any security incident affecting, or which may affect, any IT Infrastructure or data or facilities owned, leased or used by and/or provided for use by such Party, which may affect the delivery of services under this Agreement, without undue delay and in any event within [***] hours after such Party becomes aware of or suspects that a security incident has occurred. Such notification will be, in the first instance, sent by e-mail to the following e-mail address: [***] (for notification to [***]) / e-mail address: [***] (for notification to [***]) and immediately followed up by telephone to [***] (for notification to [***]).

14.9 Assignment and Successors

Neither Party may assign or transfer this Agreement in whole or in part, or the licenses granted under this Agreement, without the other Party's prior written consent *unless* such assignment is to: (a) a Third Party successor or purchaser of all or substantially all of the assets or businesses to which this Agreement relates whether pursuant to a sale of assets, merger, or other similar transaction, in which case the assigning Party will provide prior written notice to the other Party and need not obtain the other Party's consent, or (b) an Affiliate of such Party, in which case the assigning Party will provide prior written notice to the other Party and need not obtain the other Party's consent; provided that, in either case, the assigning Party remains fully liable for the performance of its obligations hereunder by such assignee. Any other assignment of this Agreement by a Party requires the prior written consent of the other Party. An assignment to an Affiliate will terminate, and all rights so assigned will revert to the assigning Party, if and when such Affiliate ceases to be an Affiliate of the assigning Party. For clarity, any assignment in violation of this Section 14.9 (Assignment and Successors) will be null, void, and of no legal effect. This Agreement will be binding upon and

inure to the benefit of the Parties and their respective legal representatives, successors and permitted assigns.

14.10 Force Majeure

Neither BioNTech nor Biotheus will be liable for failure of or delay in performing obligations set forth in this Agreement, and neither will be in breach of its obligations, to the extent such failure or delay is due to a Force Majeure; *provided, however*, that a Force Majeure will not excuse any Party from any payment obligations to the other Party under this Agreement. In event of such Force Majeure, the Party affected will use reasonable efforts to avoid or remove such causes of non-performance, and will continue to perform hereunder with reasonable dispatch whenever such causes are removed. The Party invoking such Force Majeure rights of this Section 14.10 (Force Majeure) must promptly notify the other Party by courier or overnight dispatch (e.g., Federal Express) within a period of [***] days of both the first and last day of the Force Majeure. If the affected Party's failure to perform due to such Force Majeure continues for a period of [***] days or more, then the Parties will discuss in good faith a plan to resolve the matter. Notwithstanding the foregoing, the payment of invoices due and owing hereunder shall in no event be delayed by the payer because of a Force Majeure affecting the payer.

14.11 Interpretation

The Parties acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party will not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement will be construed fairly as to each Party and not in a favor of or against either Party, regardless of which Party was generally responsible for the preparation of this Agreement. In addition, except as otherwise explicitly specified to the contrary, (i) references to a section, schedule or exhibit means a section of, or schedule or exhibit to this Agreement, unless another agreement is specified, (ii) the word "including" (in its various forms) means "including without limitation," (iii) the words "shall" and "will" have the same meaning, (iv) references to a particular statute or regulation include all rules and regulations thereunder and any predecessor or successor statute, rules or regulations, in each case as

amended or otherwise modified from time-to-time, (v) words in the singular will be held to include the plural and vice versa, and words of one gender will be held to include the other gender as the context requires, (vi) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement, (vii) references to "days" will mean calendar days, unless otherwise specified, (viii) the word "or" will not be exclusive, unless the context otherwise requires, (ix) references to "written" or "in writing" include in electronic form, (x) the titles and headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement, (xi) the terms "hereof," "hereby," "hereto," and derivative or similar words refer to this entire Agreement, including any schedules or exhibits hereto, and (xii) unless otherwise specified, "\$" is in reference to United States Dollars.

14.12 **Integration**

This Agreement, together with all agreements referred to herein and all exhibits and schedules attached hereto, sets forth the entire agreement with respect to the subject matter hereof and thereof and supersedes all other agreements and understandings between the Parties with respect to such subject matter, including the Confidentiality Agreement.

14.13 **Severability**

Each Party hereby agrees that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty, or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the Parties will substitute, by mutual consent, valid provisions for such invalid provisions, which valid provisions in their economic effect are sufficiently similar to the invalid provisions such that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions. In case such valid provisions cannot be agreed upon, the invalidity of one or several provisions of this Agreement will not affect the validity of this Agreement as a whole, unless the invalid provisions are of such essential importance to this Agreement such that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid provisions.

14.14 Further Assurances

Each of BioNTech and Biotheus agrees to duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including, the filing of such additional assignments, agreements, documents and instruments, as the other Party may at any time and from time-to-time reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes of, or to better assure and confirm unto such other Party its rights and remedies under, this Agreement.

14.15 Rights in Bankruptcy

All licenses and rights to licenses granted under or pursuant to this Agreement by the Bankrupt Party to the Non-Bankrupt Party are, and will otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code (the "**Bankruptcy Code**"), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code and that all Development Milestone Payments, Sales Milestone Payments, and Royalties will be "royalties" under the Bankruptcy Code. The Parties agree that the Non-Bankrupt Party, as a licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The Parties further agree that upon commencement of a bankruptcy proceeding by or against the Bankrupt Party under the Bankruptcy Code, the Non-Bankrupt Party will be entitled to a complete duplicate of, or complete access to (as the Non-Bankrupt Party deems appropriate), all such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments of such intellectual property will be promptly delivered to the Non-Bankrupt Party (a) upon any such commencement of a bankruptcy proceeding and upon written request by the Non-Bankrupt Party, unless the Bankrupt Party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, upon the rejection of this Agreement by or on behalf of the Bankrupt Party and upon written request by the Non-Bankrupt Party. The Bankrupt Party (in any capacity, including debtor-in-possession) and its successors and assigns (including any trustee) agrees not to interfere with the exercise by the Non-Bankrupt Party or its Affiliates of its rights and licenses to such intellectual property and such embodiments of intellectual property in accordance with this Agreement, and agrees to assist the Non-Bankrupt Party and its Affiliates in obtaining such

intellectual property and such embodiments of intellectual property in the possession or control of Third Parties as reasonably necessary or desirable for the Non-Bankrupt Party to exercise such rights and licenses in accordance with this Agreement. The foregoing provisions are without prejudice to any rights the Non-Bankrupt Party may have arising under the Bankruptcy Code or other Applicable Law.

14.16 HSR

BioNTech and Biotheus shall as soon as reasonably practicable, but in any event within [***] Business Days after the Execution Date, file a Notification and Report Form (an "HSR Filing") pursuant to the HSR Act and each Party shall use commercially reasonable efforts to obtain early termination or expiration of the waiting period under the HSR Act, including by requesting early termination of the HSR waiting period. In connection with obtaining any necessary approvals under the HSR Act, each Party shall promptly and in good faith respond to any request for additional information by the U.S. Federal Trade Commission and U.S. Department of Justice in connection with such notification and otherwise cooperate in good faith with each other and such Governmental Authority, provided that no Party shall have any obligation to (i) litigate any action or claim filed by a Governmental Authority in state or federal court alleging violation of any antitrust or other laws, (ii) sell, divest, hold separate or license any of their assets or lines of business, or (iii) change or modify any course of conduct or otherwise make any commitments to any Governmental Authority regarding future operations of BioNTech's or Biotheus' business. For the avoidance of doubt, BioNTech shall be responsible for paying any filing fees required in connection with such HSR Act filing.

For any HSR Filings required, neither BioNTech nor Biotheus shall, and each shall use reasonable best efforts to cause their respective Affiliates not to, directly or indirectly take any action, including, directly or indirectly, acquiring or investing in any person or acquiring, leasing or licensing any assets, or agreement to do any of the foregoing, if doing so would reasonably be expected to impose any material delay in the obtaining of, or significantly increase the risk of not obtaining, any required approval under the HSR Act. BioNTech and Biotheus will promptly provide the other with copies of all substantive written communications (and memoranda setting forth the substance of all substantive oral communications) between each of them, any of their subsidiaries and their respective agents, representatives and advisors, on the one hand, and any Governmental Authority, on the other hand, with respect

to this Agreement. Without limiting the foregoing, BioNTech and Biotheus shall: (i) promptly inform the other of any communication to or from the U.S. Federal Trade Commission or the U.S. Department of Justice regarding the Agreement; (ii) permit each other to review in advance any proposed substantive written communication to any such Governmental Authority and incorporate reasonable comments thereto; (iii) give the other prompt written notice of the commencement of any legal proceeding with respect to the Agreement; (iv) not agree to participate in any substantive meeting or discussion with any such Governmental Authority in respect of any filing, investigation or inquiry concerning this Agreement unless, to the extent reasonably practicable, it consults with the other Party in advance and, to the extent permitted by such Governmental Authority, gives the other Party the opportunity to attend; (v) keep the other reasonably informed as to the status of any such legal proceeding; and (vi) promptly furnish each other with copies of all correspondence, filings (except for filings made under the HSR Act) and written communications between such Party and their Affiliates and their respective agents, representatives and advisors, on one hand, and any such Governmental Authority, on the other hand, in each case, with respect to this Agreement; provided that materials required to be supplied pursuant to this clause may be redacted (1) to remove references concerning valuation, (2) as necessary to comply with contractual arrangements, (3) as necessary to comply with applicable Law, and (4) as necessary to address reasonable privilege or confidentiality concerns; provided further, that a Party may reasonably designate any competitively sensitive material provided to another party under this clause as "Outside Counsel Only".

Either Party may terminate this Agreement by notice in writing to the other Party if the expiration or termination of any applicable waiting period under the HSR Act with respect to this Agreement has not been satisfied (or if permitted by applicable Law, waived) on or before [***] days following the Execution Date (the "**Outside Date**"). If a Party terminates this Agreement pursuant to this Section 14.16 (HSR) then this Agreement shall be of no further force or effect, except that the rights and obligations of the Parties set forth in Section 10.1 (Confidential Information) and this Section 14.16 (HSR) and any relevant definitions in Article 1 (Definitions), shall survive such termination of this Agreement.

14.17 Counterparts

This Agreement may be executed simultaneously in any number of counterparts by digital or telephonic facsimile transmission (including PDF), each of which will be an original and both of which, together, will constitute a single agreement.

14.18 Relationship of the Parties

In entering into this Agreement and performing their respective duties and obligations with respect to the Agreement, the Parties are acting, and intend to be treated, as independent entities, and the activities and resources of each Party shall be managed by such Party, acting independently and in its individual capacity. The relationship between the Parties is that of independent contractors, and neither Party shall have the power to bind or obligate the other Party in any manner. Nothing contained in this Agreement shall be construed or implied to create an agency, partnership, joint venture, fiduciary, or employer-employee relationship between the Parties. Except as otherwise expressly provided in this Agreement, neither Party may make any representation, warranty or commitment, whether express or implied, on behalf of or incur any charges or expenses for or in the name of the other Party. Neither Party shall hold itself out, or take any action, contrary to the terms of this Section 14.18 (Relationship of the Parties), and neither Party shall become liable due to any such representation, warranty, commitment, act or omission made by the other Party contrary to the provisions of this Section 14.18 (Relationship of the Parties). Subject to the terms of this Agreement, the activities and resources of each Party shall be managed by such Party, acting independently and in its individual capacity.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

BIOTHEUS INC.

(普米斯生物技术(珠海)有限公司)

By: /s/ Xiaolin Liu

Name: Xiaolin Liu

Title: CEO

BIONTECH SE

By: /s/ Jens Holstein

Name: Jens Holstein

Title: CFO

By: /s/ Sierk Poetting

Name: Sierk Poetting

Title: Managing Director

[Signature Page to the Collaboration, License and Option Agreement]

Schedule 1
GLOBAL CDP & JOINT CDP

[**]

Schedule 2
EXCEPTIONS TO REPRESENTATIONS AND WARRANTIES

[**]

Schedule 3
LICENSED PATENT RIGHTS

[**]

Schedule 4
MANUFACTURING AND CMC INFORMATION

[**]

Schedule 5
BIONTECH BACKGROUND KNOW-HOW

[**]

Schedule 6
BIOTHEUS BACKGROUND IP

[**]

Schedule 7
BIONTECH COMPETITORS

[**]

Schedule 8
(A) BIOTHEUS IN-LICENSES

[**]

Schedule 9
BIOTHEUS PRESS RELEASE

[**]

Schedule 10
PM8002 LICENSED COMPOUND

[**]

Schedule 11
PM8003 LICENSED COMPOUND

[**]

*** Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) is the type of information that the Registrant treats as private or confidential.

LICENSE AND OPTION AGREEMENT

BY AND AMONG

AUTOLUS LIMITED

AUTOLUS HOLDINGS (UK) LIMITED

AND

BIONTECH SE

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LICENSE AND OPTION AGREEMENT

This **License and Option Agreement** (“**Agreement**”) is entered into this 6th day of February, 2024 (“**Execution Date**”), subject to Section 13.1(a), by and among (a) **Autolus Limited**, a company organized under the laws of England and Wales, with company number 09115837, and its registered office address at The Mediaworks, 191 Wood Lane, London, England, W12 7FP, (b) **Autolus Holdings (UK) Limited**, a company organized under the laws of England and Wales, with company number 11365111, and its registered office address at The Mediaworks, 191 Wood Lane, London, England, W12 7FP ((a) and (b) collectively “**Autolus**”); and (c) **BioNTech SE**, a corporation organized and existing under the laws of Germany, registered with the commercial register of the lower court (Amtsgericht) of Mainz under HRB 48720 and having its place of business at An der Goldgrube 12, D-55131 Mainz, Germany (“**BioNTech**”). Autolus and BioNTech are each referred to individually as a “**Party**” and together as the “**Parties**.”

Recitals

Whereas, Autolus is a clinical stage biotechnology company that owns or otherwise controls certain products and technologies applicable to CAR-T cell therapy;

Whereas, BioNTech is a biotechnology company with expertise in the research, development, and commercialization of drug products;

Whereas, pursuant to the terms and conditions of this Agreement, Autolus desires to grant, and BioNTech desires to accept, certain rights, options and licenses to develop, manufacture and commercialize products on the terms, and subject to the conditions, set out below;

Whereas, simultaneously with entering into this Agreement, Autolus and BioNTech are entering into (a) that certain securities purchase agreement (the “**Share Purchase Agreement**”), pursuant to which Autolus will sell to BioNTech, and BioNTech will purchase from Autolus, Autolus’s ordinary shares in the form of American depository shares, all in accordance with the terms and conditions set forth in the Share Purchase Agreement, and (b) that certain side letter agreement and that certain registration rights agreement pursuant to which Autolus will grant BioNTech certain rights (including registration rights) in connection with BioNTech’s purchase of Autolus’s ordinary shares in the form of American depository shares; and

Whereas, the Share Purchase Agreement contemplates a staggered signing and Initial Closing (as defined in the Share Purchase Agreement), and save as specifically provided herein, the terms of this Agreement shall become effective as of the Initial Closing.

Now, Therefore, in consideration of the mutual covenants and agreements herein contained, the Parties agree as follows.

1. Definitions

Definitions. The terms in this Agreement with initial letters capitalized have the meanings set forth below, or the meaning as designated in the indicated places throughout this Agreement.

1.1 “**Accounting Standards**” means IFRS (International Financial Reporting Standards) or U.S. GAAP (Generally Accepted Accounting Principles), as generally and consistently applied by a Party, its Affiliates, Sublicensees or Autolus Licensees (as applicable).

1.2 “**Acquirer**” means any Person that becomes an Affiliate of a Party following the Effective Date as a result of an Acquisition. “Acquirer” does not include any Person that was an Affiliate of a Party prior to such Acquisition.

1.3 “**Acquisition**” means, with respect to a Party or an Affiliate, from and after the Effective Date: (a) a merger, consolidation or similar transaction involving such Person, in which the shareholders of such Person immediately prior to such transaction cease to control (as defined in Section 1.11) such Person after such transaction; (b) a sale, transfer or other disposition of all or substantially all of the business or assets of such Person to a Third Party; or (c) a sale of a controlling (as defined in Section 1.11) interest of such Person to a Third Party. Notwithstanding the foregoing, a sale of stock of such Person to underwriters in an underwritten public offering of such Person’s stock solely for the purpose of financing does not constitute an Acquisition.

1.4 “**Activity Enhancement Licensed IP**” means the Activity Enhancement Licensed Know-How and the Activity Enhancement Licensed Patents.

1.5 “**Activity Enhancement Licensed Know-How**” means all Know-How, including [***], that is (a) Controlled by Autolus or any of its Affiliates, as of the Effective Date or during the Term, and (b) necessary or reasonably useful for (i) the Exploitation of the Activity Enhancement Licensed Technology, or (ii) the Exploitation of such Activity Enhancement Licensed Technology in an Activity Enhancement Licensed Product. Notwithstanding the foregoing, the Activity Enhancement Licensed Know-How excludes [***], except [***].

1.6 “**Activity Enhancement Licensed Patents**” means all Patents, including Patents that Cover [***], that (a) are Controlled by Autolus or any of its Affiliates, as of the Effective Date or during the Term, and (b) claim or Cover (i) Activity Enhancement Licensed Technology, (ii) Activity Enhancement Licensed Know-How, or (iii) the Exploitation of such Activity Enhancement Licensed Technology or Activity Enhancement Licensed Know-How in an Activity Enhancement Licensed Product.

1.7 “**Activity Enhancement Licensed Products**” means any pharmaceutical or biologic product that includes any Activity Enhancement Licensed Technology. For the purposes of this Agreement, [***], and *provided further* that such [***].

1.8 “**Activity Enhancement Licensed Technology**” means each module listed in Schedule 1.8.

1.9 “**Activity Enhancement Option**” means the options granted by Autolus to BioNTech in Section 6.3(d) and Section 6.3(e).

1.10 “**ADC**” means an antibody-drug conjugate, being a pharmaceutical or biologic product that contains an antibody, or an antibody derivative, that can be linked directly or indirectly to a payload such as a chemical moiety. Such antibody or antibody derivative and payload [***]. For these purposes, “antibody derivative” includes antibodies that have (a) been modified via isotype switching; (b) undergone a modification of effector function; (c) been adapted to enable the antibody to carry payloads; (d) been altered to change the expression characteristics, stability or biological half-life of the antibody; (e) been mutated using an affinity maturation strategy designed to modify the affinity of either the variable regions and/or the constant regions of the antibody for any ligands, antigens or receptors; or (f) been modified or combined to bind additional moieties. Antibody derivatives may be full length antibodies, monoclonal and polyclonal antibodies, and multispecific antibodies (*e.g.*, bi-specific antibodies), as well as antibody fragments and antibody-like fragments (including Fab, Fab’, F(ab’)₂, Fv fragments, scFv, diabodies, linear antibodies and single-chain antibodies). Antibodies and antibody derivatives can be of any origin, whether human, humanized, chimeric or otherwise.

1.11 “**Affiliate**” means, with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, “control” shall mean, direct or indirect, ownership of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interest, in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby the Person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity, or the ability to cause the direction of the management or policies of a corporation or other entity. In the case of entities organized under the laws of certain countries, the

maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%) and, in such case, such lower percentage shall be substituted in the preceding sentence; *provided*, that such foreign investor has the power to direct the management and policies of such entity.

1.12 “**Antitrust Laws**” means the Sherman Act, as amended, the Clayton Act, as amended, the HSR Act, the Federal Trade Commission Act, as amended, and all other applicable laws and regulations (including non-U.S. laws and regulations) issued by a governmental authority that are designed or intended to preserve and protect competition, prohibit and restrict monopolization, attempted monopolization, restraint of trade and abuse of dominant position, or to prevent acquisitions, mergers or other business combinations and similar transactions, the effect of which may be to lessen or impede competition or to tend to create or strengthen a dominant position or to create a monopoly.

1.13 “**Applicable Data Protection Law**” means all Applicable Laws in any jurisdiction relating to privacy or the processing or protection of Personal Data, including the General Data Protection Regulation (EU) 2016/679 (EU GDPR), the UK Data Protection Act 2018, the UK GDPR (as defined in section 3(10) (as supplemented by section 205(4)) of the UK Data Protection Act 2018), the e-Privacy Directive (2002/58/EC), the UK Privacy and Electronic Communications Regulations 2003 (SI 2003 No. 2426) as amended and the comparable Applicable Laws in other jurisdictions and all guidance issued by any applicable data protection authority, including the Information Commissioner’s Office statutory data sharing code of practice which came into force on 5 October 2021, as updated or amended from time to time.

1.14 “**Applicable Law**” means all applicable laws, statutes, rules, regulations and other pronouncements having the effect of law of any federal, national, multinational, state, cantonal, provincial, county, city or other political subdivision, agency or other body, domestic or foreign, including any applicable rules, regulations, guidelines, or other requirements of the Regulatory Authorities that may be in effect from time to time.

1.15 “**Audited Party**” has the meaning set out in Section 10.5(a).

1.16 “**Auditing Party**” has the meaning set out in Section 10.5(a).

1.17 “**Auditor**” has the meaning set out in Section 10.5(a).

1.18 “[***]” has the meaning set out in [***].

1.19 “**Autolus Indemnitees**” has the meaning set out in Section 16.2.

1.20 “**Autolus IP**” means (a) [***] Licensed IP, (b) [***] Licensed IP, (c) Safety Switch Licensed IP, (d) Activity Enhancement Licensed IP, and (e) [***] Licensed IP.

1.21 “**Autolus Know-How**” means all Know-How included within the Autolus IP.

1.22 “**Autolus Licensees**” means a licensee or sublicensee (regardless of how many tiers of (sub)licensee there are) of Autolus or any of its Affiliates; *provided* that, notwithstanding any provision to the contrary set forth in this Agreement, distributors and wholesalers will not be considered Autolus Licensees.

1.23 “**Autolus Patents**” means (a) [***] Licensed Patents, (b) [***] Licensed Patents, (c) Safety Switch Licensed Patents, (d) Activity Enhancement Licensed Patents, and (e) [***] Licensed Patents.

1.24 “**Autolus Product**” means an AUTO1/22 Product, AUTO6NG Product, and Obe-cel Product, in each case in the form in which such product exists as of the Effective Date.

1.25 “**Autolus’s Knowledge**” means the [***] knowledge [***], of any of: [***].

1.26 “**AUTO1/22 Next Gen Product**” means any AUTO1/22 Product Developed by Autolus or its Affiliates to [***].

1.27 “**AUTO1/22 Product**” means Autolus’s proprietary autologous CAR-T Cell Therapy targeting CD19 and CD22 in the form under Development as of the Effective Date, as more particularly set forth on Schedule 1.27, together with any new dosage forms, strengths, methods of manufacture, or methods of administration thereof and any improvements or modifications of such products, but excluding any AUTO1/22 Next Gen Product.

1.28 “**AUTO6NG Next Gen Product**” means any AUTO6NG Product Developed by Autolus or its Affiliates to [***].

1.29 “**AUTO6NG Product**” means Autolus’s proprietary autologous CAR-T Cell Therapy targeting GD2 in the form under Development as of the Effective Date, as more particularly set forth on Schedule 1.29, together with any new dosage forms, strengths, methods of manufacture, or methods of administration thereof and any improvements or modifications of such products, but excluding any AUTO6NG Next Gen Product.

1.30 “[***]” means [***].

1.31 “[***]” has the meaning [***].

1.32 “[***]” has the meaning [***].

1.33 “**Available**” has the meaning set out in Section 6.4(b).

1.34 “**Availability Notice**” has the meaning set out in Section 6.4(b).

1.35 “**Background IP**” has the meaning set out in Section 11.1.

1.36 “**Baseball Arbitration**” means the baseball arbitration procedure set out in Schedule 1.36.

1.37 “[***]” means [***].

1.38 “[***] **Licensed Binder**” means (a) that certain Binder of [***], and (b) [***], provided that clause (b) shall not include any Binder that (i) [***], or (ii) [***].

1.39 “[***] **Licensed IP**” means the [***] Licensed Know-How and the [***] Licensed Patents.

1.40 “[***] **Licensed Know-How**” means all Know-How, including [***], that is (a) Controlled by Autolus or its Affiliates, as of the Effective Date or during the Term, and (b) necessary or reasonably useful for (i) the Development of the [***] Licensed Binder, or (ii) the Exploitation of such Binder in a [***] Licensed Product. Notwithstanding the foregoing, the [***] Licensed Know-How [***].

1.41 “[***] **Licensed Patents**” means all Patents, including Patents that Cover [***], that (a) are Controlled by Autolus or any of its Affiliates, as of the Effective Date or during the Term, and (b) claim or Cover (i) the [***] Licensed Binder, (ii) the [***] Licensed Know-How, or (iii) the Exploitation of the [***] Licensed Binder in a [***] Licensed Product.

1.42 “[***] **Licensed Product**” means any pharmaceutical or biologic product that expresses In Vivo one or more [***] Licensed Binder(s), including any dosage strengths, presentations, formulations or methods of administration. For the purposes of this Agreement, [***], and *provided further* that [***].

1.43 “[***] **Option**” has the meaning set out in Section 6.3(b).

1.44 “[***] **Option Period**” has the meaning set out in Section 6.1.

1.45 “**Binder**” means a protein domain that is capable of binding an antigen.

1.46 “[***]” has the meaning set out in [***].

1.47 “**BioNTech Indemnitees**” has the meaning set out in Section 16.1.

1.48 “**Biosimilar Product**” means, in a particular country with respect to a particular [***] Licensed Product, a product that: (a) has received all necessary approvals by the applicable Regulatory Authorities in such country to place on the market such product as a biopharmaceutical product; (b) is marketed or sold by a Third Party that has not obtained the rights to such product as a Sublicensee or distributor of, or through any other contractual relationship with, BioNTech or any of its Affiliates or Sublicensees; and (c) is approved as a “biosimilar” (in the United States) or a “similar biological medicinal product” (in the EU) or using a comparable procedure in other countries whereby the [***] Licensed Product is the “reference medicinal product” and an expedited Regulatory Approval process for the approval of generic versions of biological products is used based on Applicable Laws and once all regulatory exclusivities and intellectual property rights for the [***] Licensed Product have expired.

1.49 “[***]” means [***].

1.50 “**BNT211**” has the meaning set out in Section 3.1(a).

1.51 “**Business Day**” means a day other than a Saturday, Sunday, or a bank or other public holiday in London, England or Mainz, Germany.

1.52 “**Calendar Quarter**” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; *provided*, that: (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first such three (3)-month period thereafter; and (b) the final Calendar Quarter of the Term shall extend from the first day of such three (3)-month period until the last day of the Term.

1.53 “**Calendar Year**” means a period of twelve (12) consecutive calendar months ending on December 31; *provided*, that: (a) the first Calendar Year of the Term shall extend from the Effective Date to December 31; and (b) the final Calendar Year of the Term shall extend from January 1 until the last day of the Term.

1.54 “**CAR**” means a chimeric antigen receptor.

1.55 “**CAR-T**” means a T-cell incorporating a CAR.

1.56 “**CAR-T Cell Therapy**” means a therapy comprising a T-cell that [***].

1.57 “[***]” means a protein product of the [***] molecule gene.

1.58 “[***]” means a protein product of the [***] molecule gene.

1.59 “[***] **Buyer**” has the meaning set out in Section 1.70.

1.60 “[***] **Licensed Binder**” means (a) that certain Binder of [***], and (b) [***], provided that clause (b) shall not include any Binder that (i) [***], or (ii) [***].

1.61 “[***] **Licensed Binder**” means (a) that certain Binder of [***], and (b) [***], provided that clause (b) shall not include any Binder that (i) [***], or (ii) [***].

1.62 “[***] **Binder** [***] **Patent**” means any Patents (a) Controlled by BioNTech or its Affiliates and (b) that claim or Cover [***] Licensed Binder and/or a [***] Licensed Binder that were made by or on behalf of BioNTech, its Affiliates, Sublicensees, or their Subcontractors unless [***].

1.63 “[***] **Competing Product**” has the meaning set out in Section 9.2(c).

1.64 “[***] **License**” has the meaning set out in Section 5.1(a).

1.65 “[***] **Licensed IP**” means the [***] Licensed Know-How and the [***] Licensed Patents.

1.66 “[***] **Licensed Know-How**” means all Know-How that is (a) Controlled by Autolus or its Affiliates, as of the Effective Date or during the Term, and (b) necessary or reasonably useful for (i) the Development of a [***] Licensed Binder and/or a [***] Licensed Binder, or (ii) the Exploitation of a [***] Licensed Product. Notwithstanding the foregoing, the [***] Licensed Know-How excludes [***].

1.67 “[***] **Licensed Patents**” means all Patents that are (a) are Controlled by Autolus or its Affiliates, as of the Effective Date or during the Term, and (b) that claim or Cover (i) a [***] Licensed Binder and/or a [***] Licensed Binder, (ii) [***] Licensed Know-How, or (iii) the Exploitation of such Binders in a [***] Licensed Product.

1.68 “[***] **Licensed Product**” means any pharmaceutical or biologic product that expresses In Vivo one or more [***] Licensed Binder(s) and/or [***] Licensed Binder(s), including any dosage strengths, presentations, formulations or methods of administration. For the purposes of this Agreement, [***] and *provided further* that [***]. For clarity, [***].

1.69 “[***] **Royalty Term**” means, on a [***] Licensed Product-by-[***] Licensed Product and country-by-country basis, the period commencing on the date of First Commercial Sale of such [***] Licensed Product in such country and expiring on [***].

1.70 “[***] **Transaction**” means [***] to a Third Party (the “[***] **Buyer**”).

1.71 “**CDR**” means complementarity determining sequences.

1.72 “**Claim**” or “**Claims**” means all Third Party demands, claims, actions, proceedings and liability (whether criminal or civil, in contract, tort or otherwise) for losses, damages, reasonable legal costs and other reasonable expenses of any nature whatsoever.

1.73 “**Clinical Study Report**” means the final clinical study report containing the results of a [***], in the form in which it is provided to Autolus by the Sponsor (or prepared by Autolus, if Autolus is the Sponsor).

1.74 “**Clinical Trial**” means any human clinical study or trial of a product, including Phase 1 Trials, Phase 2 Trials, Pivotal Trials, Phase 3 clinical trials and Phase 4 clinical trials or any other equivalent, combined or other trial a product is administered to a human subject.

1.75 “**Co-Exclusive**” means each of BioNTech and Autolus and their respective Affiliates may practice the Activity Enhancement Licensed IP with respect to products owned or controlled by such Party or one of its Affiliates, and that neither Party nor any of its Affiliates may grant Third Parties, [***], any right or license to practice the Activity Enhancement Licensed IP with any products other than products owned or controlled by such Party or one of its Affiliates.

1.76 “**Combination Product**” means: (a) a Revenue-Bearing Product in combination with [***] other therapeutically active ingredients; (b) a co-packaged Revenue-Bearing Product containing [***] separate pharmaceutical products (one of which is a Revenue-Bearing Product) in the same presentation; or (c) a Revenue-Bearing Product used as part of a treatment regimen where such Revenue-Bearing Product is approved for use with other pharmaceutical or biologic products (whether

or not each such pharmaceutical or biologic product is sold separately) and sold for a single price. For the avoidance of doubt, [***].

1.77 “**Commercialize**” means to market, promote, distribute, import, export, offer to sell or sell a product or conduct other commercialization activities with respect to a product, including activities relating to marketing, promoting, distributing, importing, exporting, offering for sale or selling a product, and “**Commercialization**” has a correlative meaning. Commercialize and Commercialization do not include Manufacture, Manufactured or Manufacturing or Develop, Development or Developed.

1.78 “**Commercially Reasonable Efforts**” means, with respect to a Party’s activities, such [***] efforts to undertake an activity as [***] would normally use to accomplish a similar objective under similar circumstances, with respect to a product that is of similar market and economic potential as the applicable product, and at a similar stage in its development or product life as such product, taking into account [***].

1.79 “**Competitive Infringement**” has the meaning set out in Section 11.4(b).

1.80 “**Confidential Information**” means all Know-How and other proprietary information and data of any kind, including of a financial, scientific, commercial or technical nature that the Disclosing Party has supplied or otherwise made available to the Recipient Party, whether made available orally, in writing or in electronic form, including information comprising or relating to concepts, discoveries, inventions, data (including Personal Data), designs or formulae in relation to this Agreement.

1.81 “**Control**” or “**Controlled**” means with respect to any Know-How, material, Patent, or other property right, the possession of the right, whether directly or indirectly, and whether by ownership, license, covenant not to sue, or otherwise (other than by operation of the license and other grants in this Agreement), for a Party or its Affiliates to grant a license, sublicense, or other right to or under such Know-How, material, Patent, or other property right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party, *provided* that, neither such Party nor its Affiliates shall be deemed to “Control” any Know-How, material, Patent, or other property right that: (a) [***] of such Party, to the extent that [***] (i) [***], or (ii) [***], in each case ((i) or (ii)), except if [***], or (b) [***], *unless*, [***] such Know-How, material, Patent, or other property right [***] Know-How, material, Patent, or other property right [***], and such license [***] the license or sublicense is under any Know-How, material, Patent [***], or other property right, and [***], as applicable.

1.82 “**Cover**” means, on a country-by-country basis, with respect to a particular subject matter at issue [***] and one or more claim(s) in a relevant Patent, that, in the absence of ownership of, or a license under, such Patent, the Exploitation of such subject matter in such country would infringe one or more issued Valid Claims of such Patent, or, as to a pending claim included in such Patent, the Exploitation of such subject matter would infringe such Patent if such pending claim were to issue in an issued patent, in such country.

1.83 “**Data Package**” means, with respect to the AUTO1/22 Product, AUTO6NG Product, AUTO1/22 Next Gen Product and AUTO6NG Next Gen Product, [***].

1.84 “**Develop**” or “**Development**” means drug research and development activities, including test method development and stability testing, assay development and audit development, toxicology, formulation, quality assurance/quality control development, technical development, process development, statistical analysis, pre-clinical and Clinical Trials, packaging development, regulatory affairs, and the preparation, filing and prosecution of Regulatory Filings. “**Developed**” has a correlative meaning. Develop, Development and Developed do not include Manufacture, Manufactured or Manufacturing or Commercialize or Commercialization.

1.85 “**Development Plan Trigger Notice**” has the meaning set out in Section 4.3.

1.86 “**Disclosing Party**” has the meaning set out in Section 12.1.

1.87 “**Dispute**” has the meaning set out in Section 17.2.

1.88 “**Dollars**” or “**\$**” means the lawful currency of the United States.

1.89 “**Drug Approval Application**” means (a) a New Drug Application, submitted to the FDA pursuant to 21 CFR § 314.50 (“**NDA**”); (b) a Biologics License Application submitted to the FDA pursuant to Section 351(a) of the Public Health Service Act and the regulations promulgated thereunder (“**BLA**”); (c) an application for authorization to market or sell a biological or pharmaceutical product submitted to a Regulatory Authority in any country or jurisdiction other than the U.S., including, with respect to the European Union, a marketing authorization application filed with the EMA pursuant to the Centralized Approval Procedure or with the applicable Regulatory Authority of a country in the European Economic Area with respect to the decentralized procedure, mutual recognition or any national approval procedure (“**MAA**”); or (d) with respect to any biological or pharmaceutical product for which an NDA, BLA or MAA has been approved by the applicable Regulatory Authority, an application to supplement or amend such NDA, BLA or MAA to expand the approved label for such biological product to include use of such biological product for an additional Indication.

1.90 “**Effective Date**” means the date of the Initial Closing.

1.91 “**Execution Date**” has the meaning set forth in the preamble.

1.92 “**EMA**” means the European Medicines Agency or any successor entity thereto.

1.93 “**Evaluation**” has the meaning set out in Section 6.1.

1.94 “**Exploit**” or “**Exploitation**” means to make, have made, import, have imported, export, have exported, use, have used, sell, have sold, offer for sale, or have offered for sale, including to research, Develop, Commercialize, register, modify, enhance, improve, Manufacture, have Manufactured, hold, or keep (whether for disposal or otherwise), or otherwise dispose of.

1.95 “**Failure to Develop**” has the meaning set out in Section 4.6(b).

1.96 “**Failure to Develop Notice**” has the meaning set out in Section 4.6(b).

1.97 “**Failure to Develop Period**” has the meaning set out in Section 4.6(b).

1.98 “**FDA**” means the U. S. Food and Drug Administration or any successor entity thereto.

1.99 “**Field**” means the treatment and prophylaxis of diseases and conditions in humans.

1.100 “**First Commercial Sale**” means, with respect to an Obe-cel Product, or [***] Licensed Product, as the case may be, in a country, the first arm’s length sale for monetary value: (a) in respect to Obe-cel Products, of such Obe-cel Product by Autolus, its Affiliates, or Autolus Licensees, or (b) in respect of [***] Licensed Products by BioNTech, its Affiliates, or their Sublicensees, as applicable to a Third Party for end use or consumption in such country following Regulatory Approval for sale of such Obe-cel Product or [***] Licensed Product in such country. Sales prior to receipt of Regulatory Approval for such product, such as so-called “treatment IND sales,” “named patient sales,” and “compassionate use sales,” shall not be construed as a First Commercial Sale.

1.101 “**Foreign Investment Laws**” means any Applicable Laws that are designed or intended to screen, prohibit, restrict or regulate actions by Persons seeking to acquire rights in or control over domestic equities, securities, entities, assets, land or other interests in order to address national security or public order goals.

1.102 “**FTE**” means a full time equivalent person-year based upon a total of [***] working hours per Calendar Year of scientific or technical work carried out by a duly qualified employee of Autolus on or directly related to the work to be conducted under the Agreement. The portion of a FTE

billable by Autolus for one (1) individual during a given accounting period shall be determined by dividing the number of hours worked directly by said individual on the work to be conducted under the Agreement during such accounting period and the number of FTE hours applicable for such accounting period based on [***]; *provided* that hours worked will not be counted by any multiplier (*e.g.*, overtime or time-and-a-half).

1.103 “**FTE Rate**” means the rate of FTE costs incurred by Autolus, which for the purpose of this Agreement shall be [***] per FTE per Calendar Year. Beginning on [***], and on [***] of each subsequent Calendar Year during the Term, the FTE Rate is subject to annual adjustment by the percentage increase in the [***] in the preceding Calendar Year.

1.104 “**Gatekeeper**” means a mutually agreed independent Third Party patent attorney.

1.105 “**GLP**” means the good laboratory practice standards set out in Schedules 1 and 2 of Directive 2004/10/EC and Directive 2004/9/EC, or the equivalent Applicable Law in the relevant jurisdiction.

1.106 “**Government Official**” means: (a) any officer, employee (including physicians, hospital administrators or other healthcare professionals), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality or subdivision of any government, military or international organization, including any ministry or department of health or any state-owned or affiliated company or hospital; (b) any candidate for political office, any political party or any official of a political party; or (c) any person acting in an official capacity on behalf of any of the foregoing.

1.107 “**Governmental Authority**” means any multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.108 “**HSR Act**” means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as codified at 15 U.S.C. §18a, as may be amended from time to time, and the rules and regulations promulgated thereunder.

1.109 “**HSR Clearance**” means the expiration or termination of all applicable waiting periods and requests for information (and any extensions thereof) under the HSR Act with respect thereto with respect to any Technologies Option or other option exercise.

1.110 “**HSR Filing**” means filings by Autolus or BioNTech with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice of a Notification and Report Form, together with all required documentary attachments thereto with respect to any Technologies Option or other option exercise.

1.111 “**IND**” means an Investigational New Drug application in the U.S. filed with the FDA or the corresponding application for the investigation of pharmaceutical or biologic products in any other country or group of countries, as defined in Applicable Law and filed with the Regulatory Authority of a given country or group of countries.

1.112 “**Indemnified Parties**” has the meaning set out in Section 16.3.

1.113 “**Indemnifying Party**” has the meaning set out in Section 16.3.

1.114 “**Indication**” means a separate and distinct disease or medical condition in humans, and [***], for which [***] with [***], as applicable.

1.115 “**Inflation Reduction Act**” means 42 U.S.C. §§ 1320f et seq., (or any amended or successor act).

1.116 “**Initial Closing**” has the meaning given to it in the Share Purchase Agreement.

1.117 “**Initial Tech Transfer Package**” means all Know-How, [***], that are in the possession of Autolus or its Affiliates at the Effective Date, that form part of the (a) [***] Licensed Know-How, (b) [***] Licensed Know-How, (c) Activity Enhancement Licensed Know-How, (d) Safety Switch Licensed Know-How, or (e) [***] Licensed Know-How and [***], or [***], in the format held by Autolus or its Affiliates on the Effective Date.

1.118 “**Initiation**” means, (a) with respect to a Phase 1 Trial, the first dosing of the [***] human subject in such Phase 1 Trial, and (b) with respect to any other Clinical Trial, the first dosing of the [***] human subject in such Clinical Trial.

1.119 “**Insolvency Event**” means, in relation to either Party, any of the following: (a) that a Party admits in writing to that the other Party that is has or will cease to function as a going concern by suspending or discontinuing its business; (b) that Party shall commence any case, proceeding or other action (i) under any existing or future law of any jurisdiction relating to bankruptcy, insolvency, reorganization or relief of debtors, seeking to have an order for relief entered with respect to it, or seeking to adjudicate it bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, winding-up, liquidation, dissolution, composition or other relief with respect to it or its debts, or (ii) seeking appointment of a receiver, trustee, custodian, conservator or other similar official for it or for all or any substantial part of its assets, or any such Party shall make a general assignment for the benefit of its creditors; (c) there shall be commenced against such Party any case, proceeding or other action of a nature referred to in clause (b) above that (1) results in the entry of an order for relief or any such adjudication or appointment or (2) remains undismitted, undischarged or unbonded for a period of [***]; (d) any case, proceeding or other action has been commenced against such Party seeking issuance of a warrant of attachment, execution, distraint or similar process against all or any substantial part of its assets that results in the entry of an order for any such relief that shall not have been vacated, discharged, or stayed or bonded pending appeal within [***] from the entry thereof; or (e) such Party shall take any action in furtherance of, or indicating its consent to, approval of, or acquiescence in, any of the acts set forth in clauses (b), (c) or (d) above.

1.120 “**Internal Program**” means an internal Autolus research program for which Autolus or any of its Affiliates has [***].

1.121 “**Intra-Group License**” means that certain License Agreement, dated [***], by and between Autolus Limited and Autolus Holdings (UK) Limited.

1.122 “**In Vivo**” means [***] in which [***] in any [***].

1.123 “**In Vivo AE Licensed Products**” has the meaning set out in Section 6.3(d).

1.124 “**JSC**” has the meaning set out in Section 2.2(a).

1.125 “**Know-How**” means all information, know-how and data, including inventions (whether patentable or not), discoveries, trade secrets, specifications, instructions, processes, formulae, materials, expertise and other technology applicable to compounds, formulations, compositions, products or to their Manufacture, Development, registration, use, Commercialization or other Exploitation, or methods of assaying or testing them or processes for their Manufacture, formulations containing them, compositions incorporating or comprising them and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data (including Personal Data), instructions, processes, formulae, expertise and information, regulatory filings and copies thereof, relevant to the Development, Manufacture, registration, use, Commercialization or other Exploitation of or which may be useful in studying, testing, Developing, producing or formulating products, or intermediates for the synthesis thereof.

1.126 “[***]” has the meaning set out in [***].

1.127 “**Losses**” has the meaning set out in Section 16.1.

1.128 “**Major Markets**” means any of [***].

1.129 “**Manufacture**” means, with respect to a compound or product, activities directed to the sourcing and purchasing of materials, producing, manufacturing, supplying, processing, compounding, filling, finishing, packing, packaging, labeling, leafleting, quality assurance, quality control testing and release, shipping, storage, and sample retention of such compound or product. “**Manufactured**” and “**Manufacturing**” have correlative meanings. Manufacture and Manufacturing do not include Develop or Developed or Commercialize or Commercialization.

1.130 “**MCSA**” has the meaning set out in Section 3.1(a).

1.131 “**MCSA Negotiation Period**” has the meaning set out in Section 3.1(a).

1.132 “**Module Option**” means (a) the Safety Switch Option, or (b) the Activity Enhancement Option.

1.133 “**Module Option Period**” has the meaning set out in Section 6.1.

1.134 “**Negotiation Trigger Notice**” has the meaning set out in Section 4.4(a).

1.135 “**Net Sales**” means, (i) with respect to any Obe-cel Product, the gross amounts [***] by Autolus, its Affiliates or Autolus Licensees to Third Party customers for sales of such Obe-cel Product, or (ii) with respect to any [***] Licensed Product, the gross amount [***] by BioNTech, its Affiliates or Sublicensees to Third Party customers for sales of such [***] Licensed Product, in each case ((i) and (ii)) less the following to the extent reasonable and customary and paid, incurred, or otherwise taken and not reimbursed by any Third Party in accordance with applicable Accounting Standards with respect to such sales;

- (a) [***];
- (b) [***];
- (c) [***];
- (d) [***];
- (e) [***],
- (f) [***]; and
- (g) [***].

Notwithstanding any provision to the contrary set forth in this Agreement, [***]. Net Sales will only be determined on the first sale by a Selling Party to (1) [***] or (2) [***]. Notwithstanding the foregoing, amounts received or invoiced by a Selling Party for the sale of such Revenue-Bearing Product to [***] for resale will not be included in the computation of Net Sales hereunder, and the amounts invoiced by [***] on such resale to [***] will be included in the computation of Net Sales hereunder. For purposes of determining Net Sales, a Revenue-Bearing Product will be deemed to be sold when [***]. Net Sales will be accounted for in accordance with the applicable Accounting Standards. A particular deduction may only be accounted for once in the calculation of Net Sales. Net Sales will exclude any Revenue-Bearing Product made available to the patient [***].

In the event that the Revenue-Bearing Product is sold as part of a Combination Product, the Net Sales of such Revenue-Bearing Product, for the purposes of determining royalty payments, shall be determined by [***].

In the event that the weighted average sale price of the Revenue-Bearing Product when sold separately in finished form can be determined but the weighted average sale price of the other active compound(s)/active ingredient(s) when sold separately in finished form cannot be determined, Net Sales shall be calculated by [***].

In the event that the weighted average sale price of the other active compound(s)/active ingredient(s) when sold separately in finished form can be determined but the weighted average sale price of the Revenue-Bearing Product when sold separately in finished form cannot be determined, Net Sales, shall be calculated by [***].

In the event that the weighted average sale price of both the Revenue-Bearing Product and the other active compound(s)/active ingredient(s) in the Combination Product, in each case, when sold separately in finished form, cannot be determined, the Net Sales of the Revenue-Bearing Product shall be determined by [***], *provided that*, [***].

The weighted average sale price for a Revenue-Bearing Product, other active compound(s)/active ingredient(s), or Combination Product [***]. When determining the weighted average sale price of a Revenue-Bearing Product, other active compound(s)/active ingredient(s), or Combination Product, the weighted average sale price shall be calculated by [***]. Any overpayment or underpayment due to [***] will be [***].

1.136 “**Next Gen Development Plan Trigger Notice**” has the meaning set out in Section 4.8(b).

1.137 “**Next Gen Negotiation Trigger Notice**” has the meaning set out in Section 4.8(c).

1.138 “**Next Gen Notification Period**” has the meaning set out in Section 4.8(b).

1.139 “**Next Gen Option Exercise Notice**” has the meaning set out in Section 4.12(a).

1.140 “**Next Gen Product**” means (a) AUTO1/22 Next Gen Product or (b) AUTO6NG Next Gen Product, as applicable.

1.141 “**Next Gen Product Agreement**” has the meaning set out in Section 4.8(c).

1.142 “**Next Gen Product Development Plan**” has the meaning set out in Section 4.8(b).

1.143 “**Next Gen Product Negotiation Period**” has the meaning set out in Section 4.9.

1.144 “**Next Gen Product Option**” has the meaning set out in Section 4.8(a).

1.145 “**Next Gen Product Option Period**” means, on a Next Gen Product-by-Next Gen Product basis, the [***].

1.146 “**Nominated Target**” has the meaning set out in Section 6.4(b).

1.147 “**Nomination Notice**” has the meaning set out in Section 6.4(b).

1.148 “**Obe-cel Buyer**” has the meaning set out in Section 1.153.

1.149 “**Obe-cel Milestone 1**” has the meaning set out in Section 7.4(a).

1.150 “**Obe-cel Milestone 2**” has the meaning set out in Section 7.4(a).

1.151 “**Obe-cel Milestone 3**” has the meaning set out in Section 7.4(a).

1.152 “**Obe-cel Product**” means the autologous CD19 CAR-T Cell Therapy known as obecabtagene autoleucl or obe-cel, as further set out in Schedule 1.152, regardless of the brand name under which it is sold, Indication, or dose.

1.153 “**Obe-cel Product Transaction**” means the [***] to a Third Party (the “**Obe-cel Buyer**”).

1.154 “**Obe-cel Revenue Interest**” has the meaning set out in Section 7.5.

1.155 “**Obe-cel Revenue Interest Term**” means, on a [***], with respect to [***] Obe-cel Product by Autolus, its Affiliates or Autolus Licensees, the period commencing on [***] and [***].

1.156 “**OP/NGOP Buyer**” has the meaning set out in Section 1.159.

1.157 “**Option Product Development Plan**” has the meaning set out in Section 4.3.

1.158 “**Option Product**” means each of (a) AUTO1/22 Product and (b) AUTO6NG Product.

1.159 “**Option Product or Next Gen Option Product Transaction**” means the [***] to a Third Party (the “**OP/NGOP Buyer**”).

1.160 “**Option Product Right**” has the meaning set out in Section 4.7(a).

1.161 “**Other AE Licensed Products**” has the meaning set out in Section 6.3(e).

1.162 “[***]” means [***].

1.163 “[***]” means [***].

1.164 “**Patents**” means (a) all national, regional and international patents and patent applications, including provisional patent applications and any and all rights to claim priority thereto, (b) all patent applications filed either from such patents, patent applications, or provisional applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, continued prosecution applications and reissue applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents, and design patents and certificates of invention, (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations, and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications or other patents resulting from post-grant proceedings ((a), (b), and (c)), and (e) any similar patent rights, including so-called pipeline protection or any importation, revalidation, confirmation, or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

1.165 “**Paying Party**” has the meaning set out in Section 10.6(b)(i).

1.166 “**Person**” means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

1.167 “**Personal Data**” shall mean any information collected or received by Autolus and provided to BioNTech as a Data Package pursuant to this Agreement and that relates to an identified or identifiable natural person in accordance with Applicable Data Protection Law.

1.168 “**Phase 1 Trial**” means a human clinical trial of a product that satisfies the requirements for a Phase 1 study as defined in 21 CFR § 312.21(a) (or any amended or successor regulations), regardless of where such clinical trial is conducted.

1.169 “**Phase 2 Trial**” means a human clinical trial of a product that satisfies the requirements for a Phase 2 study as defined in 21 CFR § 312.21(b) (or any amended or successor regulations), regardless of where such clinical trial is conducted.

1.170 “**Phase 3 Trial**” means a human clinical trial of a product that satisfies the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or any amended or successor regulations), regardless of where such clinical trial is conducted.

1.171 “**Pivotal Trial**” means a human clinical trial of a product, the principal purpose of which is a determination of safety and efficacy in the target patient population in order to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling and the filing for Regulatory Approval, or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise, including the trials referred to in 21 C.F.R. §312.21(c), as amended.

1.172 “**Product Agreement**” has the meaning set out in Section 4.4(a).

1.173 “**Product Negotiation Period**” has the meaning set out in Section 4.4(b).

1.174 “**Product Option**” has the meaning set out in Section 4.1.

1.175 “**Product Option Exercise Notice**” has the meaning set out in Section 4.5(a).

1.176 “**Product Option Period**” means the period commencing on [***] and ending on (a) with respect to AUTO1/22 Product, [***] and (b) with respect to the AUTO6NG Product, [***]; *provided*, that if BioNTech provides a Development Plan Trigger Notice pursuant to Section 4.3, then the Product Option Period for the applicable Option Product shall [***].

1.177 “[***]” means [***].

1.178 “**Qualified Indication**” means any of [***].

1.179 “**Receiving Party**” means has the meaning set out in Section 10.6(b)(ii).

1.180 “**Recipient Party**” has the meaning set out in Section 12.1.

1.181 “**Regulatory Approval**” means, with respect to a product in any country or other jurisdiction, any approval (including, where required, pricing and reimbursement approvals), registration, license or authorization from a Regulatory Authority in such country or other jurisdiction that is necessary to market and sell such product in such country or jurisdiction, including in the US, an EUA.

1.182 “**Regulatory Authority**” means any governmental agency or authority responsible for granting Regulatory Approvals for biopharmaceutical products, including the FDA, EMA, European Commission and any corresponding national or regional regulatory authorities.

1.183 “[***]” means, [***].

1.184 “**Regulatory Filings**” means, with respect to a product, any submission to a Regulatory Authority of any appropriate regulatory application with respect to such product, including any submission to a regulatory advisory board, Drug Approval Application, and any supplement or amendment thereto, including any IND, or the corresponding application in any other country or group of countries with respect to such product.

1.185 “**Research and Development Collaboration Agreement**” has the meaning set out in Section 3.2.

1.186 “**Reserved Target**” has the meaning set out in Section 6.4(c).

1.187 “**Restricted Target**” the meaning set forth in Section 6.4(d).

1.188 “[***]” have the meaning set forth in [***].

1.189 “**Revenue-Bearing Product**” means (a) Obe-cel Product when Autolus or its Affiliate, or an Autolus Licensee is the Selling Party or (b) [***] Licensed Product when BioNTech, its Affiliate, or a Sublicensee is the Selling Party.

1.190 “**ROFN Period**” has the meaning set out in Section 4.7(a).

1.191 “**Safety Switch Field**” means any and all uses, subject to the limitations set out in Schedule 1.191, Part B.

1.192 “**Safety Switch Licensed IP**” means the Safety Switch Licensed Know-How and the Safety Switch Licensed Patents.

1.193 “**Safety Switch Licensed Know-How**” means all Know-How, including [***], that is (a) Controlled by Autolus or any of its Affiliates, as of the Effective Date or during the Term, and (b) necessary or reasonably useful for (i) the Exploitation of the Safety Switch Licensed Technology, or (ii) the Exploitation of such Safety Switch Licensed Technology in a Safety Switch Licensed Product. Notwithstanding the foregoing, [***].

1.194 “**Safety Switch Licensed Patents**” means all Patents, including Patents that Cover [***], that (a) are Controlled by Autolus or any of its Affiliates, as of the Effective Date or during the Term, and (b) claim or Cover (i) the Safety Switch Licensed Technology, (ii) the Safety Switch Licensed Know-How, or (iii) the Exploitation of such Safety Switch Licensed Technology in a Safety Switch Licensed Product.

1.195 “**Safety Switch Licensed Product**” means any pharmaceutical or biologic product, in any form, that contains or incorporates any Safety Switch Licensed Technology. For the purposes of this Agreement, [***], and *provided further* that [***].

1.196 “**Safety Switch Licensed Technology**” means each regulatable control module listed in Schedule 1.191, Part A.

1.197 “**Safety Switch Option**” has the meaning set out in Section 6.3(c).

1.198 “**Sales Tax**” means any sales, goods, services, value-added, turnover, consumption, use or similar tax and any tax charged on the import or export of any goods or services.

1.199 “**Selling Party**” means (a) with respect to Obe-cel Product, Autolus, its Affiliates or Autolus Licensees, as applicable and (b) with respect to any [***] Licensed Product, BioNTech, its Affiliates or Sublicensees, as applicable.

1.200 “**Share Purchase Agreement**” has the meaning set out in the recitals to this Agreement.

1.201 “**Sponsor**” means the sponsor of the [***] of the applicable Option Product or Next Gen Product.

1.202 “**Subcommittee**” has the meaning set out in Section 2.4.

1.203 “**Subcontractor**” has the meaning set out in Section 5.3

1.204 “**Sublicensee**” means a Third Party to whom BioNTech or any of its Affiliates has granted a sublicense of any of its rights under this Agreement to Exploit [***] Licensed Products;

provided that, notwithstanding any provision to the contrary set forth in this Agreement, Subcontractors, distributors and wholesalers will not be considered Sublicensees.

1.205 “**Target**” means one or more biological targets identified by BioNTech in respect of which BioNTech wishes to exercise any Module Option, *provided* that, other than in respect of [***], if [***].

1.206 “[***]” has the meaning set out in [***].

1.207 “**Tax**” or “**Taxes**” means any taxes, duties, levies or imposts and other charges in the nature of tax and all related withholding or deductions.

1.208 “**Technologies License Agreement**” has the meaning set out in Section 6.5.

1.209 “**Technologies Option**” means (a) the [***] Option, (b) the Safety Switch Option, (c) the Activity Enhancement Option, or (d) [***] Option, as applicable.

1.210 “**Technologies Option Buyer**” has the meaning set out in Section 1.217.

1.211 “**Technologies Option Exercise Fee**” has the meaning set out in Section 6.6.

1.212 “**Technologies Option Exercise Fee Cap**” has the meaning set out in Section 6.6.

1.213 “**Technologies Option Exercise Notice**” has the meaning set out in Section 6.5.

1.214 “**Technologies Option IP**” means (a) the [***] Licensed IP, (b) the Safety Switch Licensed IP, (c) Activity Enhancement Licensed IP, and (d) [***] Licensed IP.

1.215 “**Technologies Option Period**” means the period of time commencing on the Effective Date and ending on the later of the expiration of (a) the [***] Option Period, (b) the Module Option Period, and (c) [***] Option Period.

1.216 “**Technologies Option Technology**” means the [***] Licensed Binder, [***] Licensed Binder, Safety Switch Licensed Technology, Activity Enhancement Licensed Technology, and [***] Licensed Binder.

1.217 “**Technologies Option Transaction**” means the [***] to a Third Party (the “**Technologies Option Buyer**”).

1.218 “**Term**” has the meaning set out in Section 13.1(b).

1.219 “**Territory**” means worldwide.

1.220 “**Third Party**” means any Person other than a Party or an Affiliate of a Party.

1.221 “**Third Party Evaluator**” means Subcontractors performing activities in connection with the research or development of products being researched or developed, in whole or in part, by or on behalf of BioNTech or its Affiliates alone or in conjunction with a Third Party collaborator.

1.222 “**Transferred Materials**” has the meaning set out in Section 6.2(a).

1.223 “[***]” means [***].

1.224 “[***]” means [***].

1.225 “[***]” means [***].

1.226 “[***] **Field**” means (a) the Field and (b) [***].

1.227 “[***] **Licensed Binder**” means (a) any of the Binders of [***], and (b) [***], provided that clause (b) shall not include any Binder that (i) [***], or (ii) [***].

1.228 “[***] **Licensed Binder**” means (a) any of the Binders of [***], and (b) [***], provided that clause (b) shall not include any Binder that (i) [***], or (ii) [***].

1.229 “[***] **Licensed IP**” means the [***] Licensed Know-How and the [***] Licensed Patents.

1.230 “[***] **Licensed Know-How**” means all Know-How, including [***], that is (a) Controlled by Autolus or its Affiliates, as of the Effective Date or during the Term, and (b) necessary or reasonably useful for (a) the Development of the [***] Licensed Binder and/or the [***] Licensed Binder, or (b) the Exploitation of such Binders in a [***] Licensed Product, or [***]. Notwithstanding the foregoing, [***].

1.231 “[***] **Licensed Patents**” means all Patents, including Patents that Cover [***], that (a) are Controlled by Autolus or any of its Affiliates, as of the Effective Date or during the Term, and (b) claim or Cover (i) the [***] Licensed Binder or the [***] Licensed Binder, (ii) the [***] Licensed Know-How, or (iii) the Exploitation of the [***] Licensed Binder and/or the [***] Licensed Binder in a [***] Licensed Product or [***].

1.232 “[***] **Licensed Product**” means any pharmaceutical or biologic product (a) that expresses In Vivo, or (b) is an ADC that contains, in each case of (a) and (b), the [***] Licensed Binder and/or the [***] Licensed Binder, including any dosage strengths, presentations, formulations or methods of administration, but excluding a [***]. For the purposes of this Agreement, [***] and *provided further* that [***]. For clarity, [***].

1.233 “[***] **Option**” has the meaning set out in Section 6.3(a).

1.234 “[***] **Option Period**” has the meaning set out in Section 6.1.

1.235 “[***]” means [***].

1.236 “[***]” means [***].

1.237 “[***]” means [***].

1.238 “[***]” has the meaning set forth in [***].

1.239 “**United States**” or “**U.S.**” means the United States of America, its territories and possessions.

1.240 “**Upfront Payment**” has the meaning set out in Section 7.3.

1.241 “**Upstream License Agreement**” means [***].

1.242 “**Valid Claim**” means [***] of: (a) a [***] Patent [***], which [***] and [***] and [***], *provided* that such [***] to which such [***] patent [***] is [***], excluding, however, any [***] that [***], and *provided further* that from and after such [***], unless and until [***], and [***]; or (b) any [***] Patent for which [***] any of the following: [***]; or [***], and *provided further*, that in no event will any [***] with respect to [***]. For the purposes of this Agreement, [***] shall be subject to subparagraphs (a) or (b) hereof, or [***]. For the purpose of this definition, [***].

2. Scope and Governance

2.1 **Collaboration Overview.** Under and pursuant to the terms of this Agreement: (a) the Parties shall discuss [***] (i) one or more agreements with respect to manufacturing and commercial services pursuant to Section 3.1 and (ii) a potential research and development collaboration agreement pursuant to Section 3.2; (b) Autolus shall grant BioNTech certain exclusive options to obtain certain exclusive rights to certain agreed programs Controlled by Autolus, pursuant to Article 4; (c) Autolus shall grant BioNTech an exclusive license to [***] Licensed Binders and [***] Licensed Binders pursuant to Article 5; (d) Autolus shall grant BioNTech options to obtain licenses related to (i) [***] Licensed Binders and [***] Licensed Binders, (ii) Safety Switch Licensed Technology, (iii) Activity Enhancement Licensed Technology, and (iv) [***] Licensed Binders, each in accordance with Article 6; (e) Autolus shall pay to BioNTech the Obe-cel Revenue Interest pursuant to Section 7.5; and (f) BioNTech shall pay the license payment to Autolus set out in Section 9.1, purchase shares in Autolus set out in the Share Purchase Agreement, as further set out in the Recitals, and make the other payments set out under this Agreement in accordance with the terms hereof.

2.2 Joint Steering Committee.

(a) Within [***], the Parties shall establish a joint steering committee (the “JSC”) to provide a forum for communication between the Parties and to oversee the relationship between the Parties; *provided, however*, that the JSC shall have no authority to amend this Agreement. The JSC is formed to aid in the exchange of information and discussions by the Parties [***]. The JSC shall disband upon the later of (i) [***], and (ii) [***]; *provided*, that upon BioNTech’s written request, the term of the JSC shall continue for [***] beyond such period.

(b) The JSC shall be comprised of an equal number of representatives from each of Autolus and BioNTech. The exact number of such representatives shall be [***] for each Party, or such other number as the Parties may agree. Autolus and BioNTech shall each designate one of its JSC members as co-chairperson of the JSC. Each Party may replace any or all of its representatives or appoint a proxy at any time by giving prior written notification to the other Party. Each Party may, in its reasonable discretion, invite other employees and agents of such Party who are under written obligations of confidentiality to attend meetings of the JSC.

(c) From [***] until [***], the JSC will hold meetings on a [***] basis, and thereafter shall hold meetings [***], in each case unless otherwise agreed by the Parties. All meetings will be held by videoconference, telephone, web conference, or face to face, unless otherwise agreed by the JSC. The co-chairpersons of the JSC will set the agenda for meetings of the JSC. The co-chairpersons will issue minutes of each meeting of the JSC [***] following each meeting. The minutes will be considered as accepted if, within [***] following receipt, no one has objected in writing (including by electronic mail) to the co-chairpersons disputing the accuracy of such minutes. The minutes of each JSC meeting are the Confidential Information of both Parties.

(d) The JSC will:

(i) review and discuss Autolus’s [***] updates provided under Section 4.2(a), any Data Package provided under Section 4.2(b), and any commencement by Autolus of Development activities on any Next Gen Product notified under Section 4.2(c);

(ii) following delivery of any Development Plan Trigger Notice or Next Gen Development Plan Trigger Notice, review and discuss the Option Product Development Plan or Next Gen Development Plan (as applicable), in accordance with Section 4.3 and Section 4.8(c) respectively;

(iii) review the [***] updates provided by BioNTech pursuant to Section 6.2(d);

(iv) review and discuss the report regarding the Obe-cel Product set forth in Section 7.1, and any updates to such report;

- (v) review and discuss [***] updates on Development of Obe-cel Product with respect to Indications other than [***];
- (vi) during the [***], including Autolus's [***] updates provided under Section 8.2;
- (vii) review and discuss any [***] under Section 3.1(b), and oversee [***] pursuant to Section 3.1(b);
- (viii) review and discuss each report provided by BioNTech under Section 5.11;
- (ix) review and discuss [***];
- (x) perform other responsibilities specifically assigned to the JSC pursuant to this Agreement or as may be mutually agreed upon by the Parties in writing from time to time.

(e) Without prejudice to any obligation on Autolus to provide any of the information referenced for review and discussion at the JSC on particular timelines elsewhere in this Agreement, Autolus shall ensure that such information for discussion and review will be made available to BioNTech in writing reasonably in advance of each JSC meeting.

(f) The Parties will [***].

2.3 **Alliance Managers.** Within [***], each Party shall appoint an individual (who is not a member of the JSC) who possesses a general understanding of this Agreement to act as the alliance manager for such Party ("**Alliance Manager**"). Each Alliance Manager may attend meetings of the JSC as a nonvoting observer and the Alliance Managers may bring to the attention of the JSC any matters or issues such Alliance Manager reasonably believes should be discussed. The Alliance Managers will be a key point of contact for the Parties regarding the contractual and business aspects of the collaboration during the Term. Each Party may replace its Alliance Manager at any time by giving prior written notification to the other Party.

2.4 **Subcommittees.** The JSC may establish one or more subcommittees of the JSC (each a "**Subcommittee**"). Each Subcommittee shall be established on mutually agreed terms, and have agreed specific responsibilities, *provided*, that no Subcommittee shall have the authority to amend this Agreement or any other agreement.

3. Collaboration Agreements

3.1 Manufacturing and Commercial Services Agreement.

(a) During the period commencing on the Effective Date and ending on the eighteen (18) month anniversary of the Effective Date ("**MCSA Negotiation Period**"), the Parties shall [***] negotiate the terms of and execute a joint manufacturing and commercial services agreement ("**MCSA**") pursuant to which (i) Autolus may obtain access to BioNTech's manufacturing and commercial site services capabilities for Autolus's CAR-T products, and (ii) BioNTech may obtain access to Autolus's manufacturing and commercial site services capabilities for BioNTech's CAR-T products, including the product known as BNT211 ("**BNT211**"), including, in each case, [***]. The MCSA will reflect the terms set forth on Schedule 3.1.

(b) During the MCSA Negotiation Period, Autolus (1) shall provide updates to the JSC on the progress of its Manufacturing facilities to allow BioNTech to monitor the progress of such facilities and (2) [***]. For the avoidance of doubt, subject to Autolus reserving the requisite capacity for BioNTech, (i) this Section 3.1(b) does not prevent, inhibit or otherwise affect Autolus's ability to Manufacture any product that has been Developed by Autolus or its Affiliates (including Obe-cel Product), whether for sale by itself or any Third Party, (ii) [***], and (iii) [***] after [***], the Parties shall [***], which shall [***].

(c) Autolus will [***] ensure that its manufacturing facility is ready and available to manufacture BNT211 by [***] such that the batches produced at Autolus's manufacturing facility can be [***], subject to (i) Section 3.1(d), (ii) BioNTech fulfilling its obligations in [***], and (iii) BioNTech [***]. If a Party's performance of its obligations under [***] is adversely affected in a material manner by the other Party's failure to perform its obligations under this Agreement, then the impact of such performance failure will be taken into account in determining whether such first Party has used the required efforts to perform any such affected obligations, but only to the extent such other Party's performance failure is the cause of such first Party's failure to meet such obligations and such first Party continues to use the required efforts to reduce the impact of the other Party's performance failure.

(d) If the MCSA is not entered into within [***] following [***], then the timeline of [***] in Section 3.1(c) shall be [***].

(e) If upon expiry of the MCSA Negotiation Period, the Parties are unable to agree the terms of the MCSA, BioNTech may, in its sole discretion, refer the terms of the MCSA for resolution using Baseball Arbitration, which referral must occur within [***] of expiry of the MCSA Negotiation Period. If (i) BioNTech does not refer the terms of the MCSA for resolution using Baseball Arbitration within [***] of expiry of the MCSA Negotiation Period, or (ii), BioNTech chooses not to enter into the MCSA within [***] after the arbitrator has given a final decision in Baseball Arbitration then, without any further action required on the part of either Party, the obligations set out in Section 3.1(a), Section 3.1(b) and Section 3.1(c) shall expire and, if an MCSA has not been entered into by such date, then there shall be no further obligation to continue negotiations on either Party and Autolus, at its sole discretion, may enter into an agreement with a Third Party pursuant to which Autolus would Manufacture a Third Party's CAR-T Cell Therapy.

3.2 **Research and Development Collaboration Agreement.** During [***], the Parties shall discuss [***] the terms, including financial terms, of a research and development collaboration agreement regarding products that utilize the expertise of both Parties ("**Research and Development Collaboration Agreement**"), *provided* that neither Party is required to enter into such Research and Development Collaboration Agreement, and the obligation to discuss shall expire at the end of such [***] period.

4. Product Options

4.1 **Product Options.** With effect from the Effective Date, Autolus hereby grants to BioNTech, on an Option Product-by-Option Product basis, the exclusive option to obtain the exclusive right to co-fund certain development costs in respect of the relevant Option Product in return for a [***] profit sharing arrangement, and to obtain the exclusive option to co-promote and co-commercialize the Option Product, in each case, for all oncology Indications and subject to and as further set out in this Article 4 and Schedule 4.4(a) (each, a "**Product Option**").

4.2 Provision of Data.

(a) Autolus shall, within [***], deliver to BioNTech, all information and data received or otherwise Controlled by Autolus in relation to the Development of the Option Products, [***], in the formats such information and data are held by Autolus [***]. During the applicable Product Option Period, Autolus shall provide additional data received by or otherwise Controlled by Autolus in relation to the Development of the Option Products to BioNTech [***] following such data becoming available to Autolus. Autolus will provide the JSC with updates on the progress of the Sponsor's activities in relation to such Option Product or Next Gen Product, as applicable, every [***] during the applicable (i) Product Option Period for each Option Product, and, (ii) Next Gen Product Option Period for each Next Gen Product. Autolus will also provide the JSC with updates on the progress of the Development of each Option Product and Next Gen Product [***] from [***] until the end of the Product Option Period for the applicable Option Product and from [***] until the end of the Next Gen Product Option Period for the applicable Next Gen Product. Autolus shall, during the applicable Product Negotiation Period on an Option Product-by-Option Product basis and, during the applicable Next Gen Product Negotiation Period on a Next Gen Product-by-Next Gen Product basis, on BioNTech's request, request from the Sponsor any additional relevant data that the Sponsor has in relation to the Option Products or Next Gen Products, as applicable, which has not been provided to Autolus. On BioNTech's request during the applicable

Product Negotiation Period or Next Gen Product Negotiation Period, Autolus will [***] facilitate access for BioNTech to the Sponsor's principal investigators working on the Development of the applicable Option Products and Next Gen Products. Autolus will [***] provide BioNTech with [***] (1) of AUTO6NG Product during the applicable Product Option Period and any applicable ROFN Period, and (2) of any Next Gen Product during the applicable Next Gen Product Option Period. To the extent that any data to be provided under this Section 4.2(a), Section 4.2(b) or Section 4.7(b) constitutes Personal Data, Autolus shall only be obliged to deliver such Personal Data to BioNTech to the extent to which it can be delivered in compliance with Applicable Data Protection Law. If the current formats are not compatible with the transfer of such information and data to BioNTech in compliance with Applicable Data Protection Law, then Autolus shall [***] (A) to obtain such information and data in an anonymized or other format that (x) can be transferred to BioNTech and (y) results in the applicable information and data no longer constituting Personal Data under Applicable Data Protection Law, or (B) to facilitate an appropriate data transfer agreement under which such data can be provided to BioNTech in compliance with Applicable Data Protection Law, *provided that* [***].

(b) Autolus shall deliver to BioNTech the applicable Data Package: (i) within [***] after [***], with respect to the AUTO1/22 Product, (ii) [***], with respect to the AUTO6NG Product, or (iii) during the applicable Next Gen Product Option Period, [***]. Autolus shall provide reasonable assistance to BioNTech in analyzing each Data Package, at BioNTech's written request and [***].

(c) If Autolus commences Development activities on any Next Gen Product during the Next Gen Product Option Period, it shall inform BioNTech [***].

4.3 Development Plan. On an Option Product-by-Option Product basis, at any time during the applicable Product Option Period after BioNTech has received the relevant Data Package pursuant to Section 4.2(b), BioNTech may notify Autolus in writing that it wishes to receive a Development plan for such Option Product (a "**Development Plan Trigger Notice**"). Within [***] after Autolus receives a Development Plan Trigger Notice, Autolus shall provide to BioNTech a reasonably detailed written Development plan and associated budget for the applicable Option Product (the "**Option Product Development Plan**"). The Option Product Development Plan would include [***]. Upon BioNTech's request, the Parties, through the JSC, would discuss the Option Product Development Plan and associated budget and Autolus shall [***]. For clarity, [***]. If BioNTech provides a Development Plan Trigger Notice, and Autolus does not, at such time, intend to Develop further such Option Product, then Section 4.7 applies. For the period from provision of the Data Package until the earlier of: (i) the relevant Product Option Period expires without a Development Plan Trigger Notice being received by Autolus, (ii) [***] after BioNTech's receipt of the applicable Option Product Development Plan, if no Negotiation Trigger Notice is received by Autolus, or (iii) expiry of the Product Negotiation Period and any period during which a Baseball Arbitration procedure is ongoing with respect to such Option Product, Autolus shall not grant a Third Party rights to Exploit the relevant Option Product without BioNTech's prior written consent, [***].

4.4 Negotiation of Product Agreement.

(a) **Negotiation Trigger Notice.** Within [***] after BioNTech's receipt of the Option Product Development Plan, BioNTech may notify Autolus in writing that it wishes to enter into exclusive negotiations with Autolus to finalize the terms of and execute an agreement in respect of the Exploitation of a particular Option Product for the treatment of one or more oncology Indications, providing for co-funding and [***] profit share arrangements and an exclusive option for BioNTech to co-promote and co-commercialize (each a "**Negotiation Trigger Notice**"), which agreement shall include the terms set out in Schedule 4.4(a) (each a "**Product Agreement**"). The Option Product Development Plan would be included as an initial Development plan to the Product Agreement.

(b) **Negotiation of Product Agreement.** The Parties shall, on an Option Product-by-Option Product basis, negotiate exclusively [***] for a period of [***] from the date of Autolus's receipt of the Negotiation Trigger Notice ("**Product Negotiation Period**"), to agree the definitive terms of the applicable Product Agreement. If the anticipated start date for the Development activities included in the Option Product Development Plan is more than [***] after BioNTech's receipt of the Option Product Development Plan, the Parties would [***].

(c) **Referral to Baseball Arbitration.** If, upon expiry of the applicable Product Negotiation Period, the Parties are unable to agree the terms of such Product Agreement, BioNTech may, in its sole discretion, refer the terms of the Product Agreement ([***) for resolution using Baseball Arbitration, which referral must occur within [***) of expiry of the applicable Product Negotiation Period.

4.5 Option Exercise.

(a) **Option Exercise Notice.** Within [***) after (i) the Parties have agreed on a Product Agreement for the applicable Option Product or (ii) the arbitrator has given a final decision in Baseball Arbitration, as applicable, BioNTech may notify Autolus in writing that it wishes to execute the applicable Product Agreement (a “**Product Option Exercise Notice**”). If BioNTech provides such a Product Option Exercise Notice, then the Parties shall execute such Product Agreement within [***) after Autolus’s receipt of the Product Option Exercise Notice.

(b) **Option Exercise Fee.** BioNTech shall pay Autolus the applicable option exercise fee set forth below for the corresponding Product Agreement within [***) after the receipt of an invoice from Autolus following the execution of such Product Agreement:

Option Product	Option Exercise Fee
AUTO1/22	[***)
AUTO6NG	[***)

4.6 Failure to Exercise Option or Rejection of Baseball Arbitration.

(a) If:

- (i) Autolus does not receive a Development Plan Trigger Notice during the applicable Product Option Period,
- or
- (ii) Autolus does not receive a Negotiation Trigger Notice within [***) after BioNTech’s receipt of an Option Product Development Plan, or
- (iii) the Parties fail to enter into a Product Agreement during the applicable Product Negotiation Period and BioNTech does not refer such matter for resolution using Baseball Arbitration in the period described in Section 4.4(c), or
- (iv) Autolus does not receive a Product Option Exercise Notice within [***) after the Parties have agreed on a Product Agreement for the applicable Option Product or the arbitrator has given a final decision in Baseball Arbitration, or
- (v) BioNTech chooses not to enter into the applicable Product Agreement within [***) after the Parties have agreed on a Product Agreement for the applicable Option Product or the arbitrator has given a final decision in Baseball Arbitration,

then in each case of (i)–(v), with effect from the date of expiry of such period, and without any further action required on the part of either Party, the applicable Product Option shall expire and then the terms of this Article 4 shall no longer apply to such Option Product and, without limiting the generality of the foregoing, Autolus may commence Development of such Option Product or enter into an agreement with a Third Party for such Option Product, on terms determined at Autolus’s sole discretion without further reference to BioNTech, save as provided in Section 4.6(b).

(b) If Autolus elects to commence Development of an Option Product in accordance with Section 4.6(a)(ii)–(v) where Autolus received a Development Plan Trigger Notice, but for which the Parties have not entered into a Product Agreement, (i) Autolus shall, on BioNTech’s written request during the [***] from the date of expiry of the applicable period in Section 4.6(a), provide BioNTech with a report on Autolus’s Development spend under the applicable Development Plan reconciled against the budget for the applicable Development Plan, and [***] (a “**Failure to Develop**”), Autolus will notify BioNTech in writing (a “**Failure to Develop Notice**”) and the provisions of Section 4.2(b) and Section 4.8 shall apply to any Next Gen Product of such Option Product, for which Autolus obtains, within [***] after the BioNTech’s receipt of the Failure to Develop Notice (the “**Failure to Develop Period**”), sufficient data and information to provide BioNTech with a Data Package.

4.7 Rights of BioNTech if Autolus does not wish to Develop.

(a) If Autolus notifies BioNTech pursuant to Section 4.3 that it does not, at the time of receipt by Autolus of a Development Plan Trigger Notice, intend to Develop further such Option Product, then Autolus shall and hereby does grant BioNTech (i) a right of first negotiation, as set out in this Section 4.7, in relation to such Option Product if Autolus intends (1) [***], or (2) [***] ((1) and (2) collectively, an “**Option Product Right**”), and (ii) the right to negotiate a Product Agreement in accordance with Sections 4.3–4.6 if Autolus intends to Develop such Option Product itself or with or through any Affiliate, in the case of both (i) and (ii) for a period of [***] commencing on the date of receipt by Autolus of the applicable Development Plan Trigger Notice (the “**ROFN Period**”), subject to and as further set out in Section 4.7(b). Notwithstanding the foregoing, the rights in this Section 4.7 do not apply to an Acquisition of Autolus or its Affiliate. For clarity, Section 4.7 remains in full force and effect following an Acquisition of Autolus or its Affiliate.

(b) If Autolus notifies BioNTech pursuant to Section 4.3 that it does not, at the time of receipt by Autolus of a Development Plan Trigger Notice, intend to Develop further such Option Product, and thereafter during the ROFN Period Autolus intends to Develop such Option Product itself or with or through any Affiliate or to grant any Third Party an Option Product Right, then, prior to commencing such Development or engaging in discussions or entering into any agreement with any Third Party for the grant of such rights (a “**Restricted Act**”), Autolus shall provide BioNTech with prior written notice and all material information and data relating to such Option Product then in its possession (to the extent not previously provided pursuant to Section 4.2) and, (i) in the event that Autolus intends to grant any Third Party an Option Product Right, for a period of [***] after receipt of such notice and information, BioNTech has an exclusive right of first negotiation to enter into a definitive agreement with Autolus granting BioNTech rights in relation to such Option Product, and during such [***], Autolus would negotiate [***] with BioNTech and would not perform any Restricted Act, and (ii) in the event that Autolus intends to Develop such Option Product itself or with or through any Affiliate, to an option on the terms set out in Schedule 4.4(a), in which case the provisions of Sections 4.3–4.6 shall apply, *mutatis mutandis*, provided that BioNTech provides a Development Plan Trigger Notice to Autolus within [***] of receiving written notice and all material information and data from Autolus regarding Autolus’s proposed further Development of such Option Product.

(c) Notwithstanding the ROFN Period, if the Parties fail to enter into a definitive agreement prior to (i) in the case of Autolus intending to Develop such Option Product through the grant of any Option Product Rights to any Third Party, the expiration of the [***] period set forth in Section 4.7(b), and (ii) in the case of Autolus intending to Develop such Option Product itself or with or through any Affiliate, the date of expiry of the applicable period set forth in Sections 4.6(a)(i)–4.6(a)(v), *mutatis mutandis*, then (1) for a period of [***] after the ROFN Period, Autolus will notify BioNTech if Autolus intends to grant a Third Party a Product Option Right, and (2) all of the terms of this Section 4.7 shall no longer apply to such Option Product and, for clarity, and without limiting the generality of the foregoing, Autolus may commence Development of such Option Product, engage in discussions with a Third Party or enter into an agreement with a Third Party for such Option Product, on terms determined at Autolus’s sole discretion.

4.8 Next Generation Products Option.

(a) **Next Gen Product Option and Next Gen Product Development Plan** . Autolus hereby grants to BioNTech, on a Next Gen Product-by-Next Gen Product basis, the exclusive option in relation to any Next Gen Product for which Autolus provides BioNTech with a Data Package pursuant to Section 4.2(b), to obtain the exclusive right to co-fund certain development costs in respect of the relevant Next Gen Product in return for a [***] profit sharing arrangement, in each case, for all oncology Indications, and obtain the exclusive option to co-promote and co-commercialize such Next Gen Product for all oncology Indications, in each case, subject to and as set out in this Section 4.8 (“**Next Gen Product Option**”).

(b) **Next Gen Product Development Plan**. At any time during the [***] period after BioNTech’s receipt of a Data Package for a Next Gen Product pursuant to Section 4.2(b) (the “**Next Gen Notification Period**”), BioNTech may notify Autolus in writing that it wishes to receive a Development plan for such Next Gen Product (a “**Next Gen Development Plan Trigger Notice**”). Within [***] after Autolus receives a Next Gen Development Plan Trigger Notice, Autolus shall provide to BioNTech a reasonably detailed written Development plan and associated budget for the applicable Next Gen Product (the “**Next Gen Product Development Plan**”). The Next Gen Product Development Plan would include [***]. Upon BioNTech’s request, the Parties, through the JSC, would discuss the Next Gen Product Development Plan and associated budget and Autolus shall [***]. For clarity, [***]. For the period from receipt by Autolus of a Next Gen Development Plan Trigger Notice until the earlier of (i) [***] after BioNTech’s receipt of the applicable Next Gen Product Development Plan, if no Next Gen Negotiation Trigger Notice is received by Autolus, or (ii) the expiry of the Next Gen Product Negotiation Period and any period during which a Baseball Arbitration procedure is ongoing with respect to such Next Gen Product, Autolus shall not grant a Third Party rights to Exploit the relevant Next Gen Product without BioNTech’s prior written consent, [***].

(c) **Negotiation Trigger Notice**. Within [***] after BioNTech’s receipt of the Next Gen Product Development Plan, BioNTech may notify Autolus in writing that it wishes to enter into exclusive negotiations with Autolus to agree the terms of and execute an agreement in respect of the Exploitation of the applicable Next Gen Product for the treatment of one or more oncology Indications, providing for co-funding and [***] profit share arrangements and an exclusive option for BioNTech to co-promote and co-commercialize (each a “**Next Gen Negotiation Trigger Notice**”), which agreement shall include the terms set out in Schedule 4.4(a) (each a “**Next Gen Product Agreement**”). The Next Gen Product Development Plan would be included as an initial Development plan to the Next Gen Product Agreement.

4.9 **Negotiation of Next Gen Product Agreement** . The Parties shall, on a Next Gen Product-by-Next Gen Product basis, negotiate exclusively [***] for a period of [***] from the date of Autolus’s receipt of the Next Gen Negotiation Trigger Notice to agree the definitive terms of the applicable Next Gen Product Agreement (such period and any mutually agreed extension, the “**Next Gen Product Negotiation Period**”), to agree the definitive terms of the applicable Next Gen Product Agreement. If the anticipated start date for the Development activities included in the Next Gen Product Development Plan is more than [***] after BioNTech’s receipt of the Next Gen Product Development Plan, the Parties would [***].

4.10 **Referral to Baseball Arbitration**. If, upon expiry of the applicable Next Gen Product Negotiation Period, the Parties are unable to agree the terms of such Next Gen Product Agreement, BioNTech may, in its sole discretion, refer the terms of the Next Gen Product Agreement ([***]) for resolution using Baseball Arbitration, which referral must occur within [***] of expiry of the applicable Next Gen Product Negotiation Period.

4.11 **Failure to Exercise Option or Rejection of Baseball Arbitration**. If:

(a) Autolus does not receive a Next Gen Development Plan Trigger Notice during the applicable Next Gen Notification Period, or

(b) Autolus does not receive a Next Gen Negotiation Trigger Notice within [***] after BioNTech’s receipt of a Next Gen Product Development Plan, or

(c) the Parties fail to enter into a Next Gen Product Agreement during the applicable Next Gen Product Negotiation Period and BioNTech does not refer such matter for resolution using Baseball Arbitration in the period described in Section 4.10, or

(d) Autolus does not receive a Next Gen Option Exercise Notice within [***] after the Parties have agreed on a Next Gen Product Agreement for the applicable Next Gen Product or the arbitrator has given a final decision in Baseball Arbitration, or

(e) BioNTech chooses not to enter into the applicable Next Gen Product Agreement within [***] after the Parties have agreed on a Next Gen Product Agreement for the applicable Next Gen Product or the arbitrator has given a final decision in Baseball Arbitration,

then in each case of (a)–(e), with effect from the date of expiry of such period, and without any further action required on the part of either Party, the applicable Next Gen Product Option shall expire and then the terms of this Article 4 shall no longer apply to such Next Gen Product and, without limiting the generality of the foregoing, Autolus may commence Development of such Next Gen Product or enter into an agreement with a Third Party for such Next Gen Product, on terms determined at Autolus’s sole discretion without further reference to BioNTech.

4.12 Next Gen Option Exercise.

(a) **Option Exercise Notice.** Within [***] after (i) the Parties have agreed on a Next Gen Product Agreement for the applicable Next Gen Product or (ii) the arbitrator has given a final decision in Baseball Arbitration, as applicable, BioNTech may notify Autolus in writing that it wishes to execute the applicable Next Gen Product Agreement (a “**Next Gen Option Exercise Notice**”). If BioNTech provides such a Next Gen Option Exercise Notice, then the Parties shall execute such Next Gen Product Agreement within [***] after Autolus’s receipt of the Next Gen Option Exercise Notice.

(b) **Next Gen Option Exercise Fee.** BioNTech shall pay Autolus the applicable option exercise fee set forth below for the corresponding Next Gen Product Agreement within [***] after the receipt of an invoice from Autolus following the execution of such Next Gen Agreement:

Next Gen Product	Option Exercise Fee
AUTO1/22	[***]
AUTO6NG	[***]

4.13 **If Autolus does not wish to Develop.** If BioNTech provides a Next Gen Development Plan Trigger Notice, and Autolus does not, at such time, intend to Develop further such Next Gen Product, then Autolus shall provide BioNTech with written notice and all material information and data relating to such Next Gen Product then in Autolus’s possession and, for a period of [***] after receipt of such notice and information, BioNTech has a right of first negotiation to such Next Gen Product to obtain rights in such Next Gen Product. During such [***], Autolus may not perform any Development, engage in discussions or enter into any agreement with any Third Party for the grant of any rights in relation to such Next Gen Product.

5. License To [***] and [***] Binders

5.1 **License Grant.** Subject to the terms and conditions of this Agreement, with effect from the Effective Date, Autolus hereby grants to BioNTech:

(a) an exclusive (including as to Autolus and its Affiliates), sub-licensable (subject to Section 5.3), payment-bearing, worldwide license under the [***] Licensed IP (i) to Develop the [***] Licensed Binder and the [***] Licensed Binder in connection with a [***] Licensed Product, and (ii) to

Exploit [***] Licensed Products directed to [***], in each case of (i) and (ii), in the Field in the Territory (“[***] License”); and

(b) a non-exclusive, non-transferable, limited, non-sublicensable (other than to Third Party Evaluators) license under the [***] Licensed IP to research and Develop (only up to and including [***]) a CAR-T Cell Therapy; *provided* that [***]; *provided further* that [***].

5.2 **Right of Negotiation.** If BioNTech, its Affiliates or Sublicensees wishes to Exploit any [***] Licensed Product in combination with a CAR-T Cell Therapy that [***] (the “Autolus [***] CAR-T”), then prior to [***], BioNTech shall provide Autolus with prior written notice and grants, and shall procure the grant of, to Autolus, for a period of [***] after receipt of such notice, a right of first negotiation to, [***], negotiate and enter into an agreement with BioNTech, its Affiliate or Sublicensee (as applicable) for Autolus or its Affiliate to be BioNTech’s partner for such combination therapy, whereby [***] Licensed Product would be used in combination with such Autolus [***] CAR-T. Prior to or during such [***] period, BioNTech, its Affiliates and Sublicensees shall [***].

5.3 **Sublicense Rights; Subcontracting.** Subject to the terms and conditions of this Agreement, BioNTech may sublicense the rights granted to it by Autolus under Section 5.1, including in connection with subcontracting to Third Parties whose business is to provide services to other entities, including contract research organizations, contract laboratory testing providers, contract manufacturing organizations, contract sales force providers, contract employees, and scientific, regulatory or other expert consultants and professional advisors (“Subcontractor”) the rights or performance of tasks and obligations with respect to the Exploitation of [***] Licensed Products; *provided* that:

(a) BioNTech is not permitted to grant a sublicense under the rights granted to it by Autolus under Section 5.1 that permits the Sublicensee to Develop or otherwise use a [***] Licensed Binder and/or a [***] Licensed Binder:

(i) for any purpose *other than* [***], and

(ii) for any purpose *other than* [***] under: (1) [***] described in clause (i), or (2) [***] described in clause (i), *provided* that, if [***], then unless [***];

(b) any such sublicenses shall be in writing and be consistent with the applicable terms and conditions of this Agreement;

(c) BioNTech shall remain responsible for the performance of all of its Sublicensees to the same extent as if such activities were conducted by BioNTech, and, as between the Parties, BioNTech shall remain responsible for any payments due to Autolus under this Agreement with respect to activities of any Sublicensees; and

(d) within [***] after the execution of any sublicense agreement with a Sublicensee, BioNTech shall provide Autolus with a copy of such sublicense agreement, *provided* that BioNTech may redact any terms of such sublicense agreement (i) [***] or (ii) [***].

5.4 **Retention of Rights.** Autolus hereby expressly reserves the right to practice, and to grant licenses under, the [***] Licensed IP outside the scope of the licenses granted to BioNTech pursuant to Section 5.1.

5.5 **No Implied Licenses.** Except as expressly provided in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication, estoppel, or otherwise, under or to any Patents, Know-How, information, or other intellectual property owned or controlled by the other Party. BioNTech shall not, nor shall it permit any of its Affiliates or Sublicensees to, practice any Patents or Know-How licensed to it by Autolus outside the scope of the licenses granted to it under this Agreement, except as permitted under Applicable Law.

5.6 **Scope.** For clarity, subject to the terms of this Agreement (including Section 5.1 and Section 5.2), the licenses granted to BioNTech by Autolus to Exploit [***] Licensed Products extend to BioNTech being able to Exploit [***] Licensed Products in conjunction with BioNTech's own products, product components, or other technologies or Third Party products, product components, or other technologies, in each case, whether through co-formulation, co-packaging, co-administration, or any other use as part of a Combination Product or combination therapy.

5.7 [***]. In the event that [***], BioNTech hereby grants to Autolus a non-exclusive, [***] irrevocable, perpetual license in the Field in the Territory under [***] Binder [***] Patent in the field of [***] only in the Territory solely for Autolus, its Affiliates and Autolus Licensees to Exploit [***] in the field of [***] in the Territory. Any sublicenses shall be in writing and be consistent with the applicable terms and conditions of this Agreement. As used in this Section 5.7, "[***]" means [***].

5.8 **Transfer of Know-How.** [***], Autolus shall transfer, disclose and otherwise make available to BioNTech the Initial Tech Transfer Package. If, following such initial transfer BioNTech notifies Autolus, in writing, of any specific (a) [***] Licensed Know-How, (b) [***] Licensed Know-How, (c) Activity Enhancement Licensed Know-How, (d) Safety Switch Licensed Know-How or (e) [***] Licensed Know-How, in Autolus's or its Affiliates' Control, or Autolus identifies such Know How, in each case which has not previously been provided to BioNTech ([***]), then Autolus shall [***] disclose to BioNTech such Know-How. At BioNTech's written request [***], Autolus shall provide reasonable assistance to BioNTech in analyzing and understanding the (i) [***] Licensed Know-How, (ii) [***] Licensed Know-How, (iii) Activity Enhancement Licensed Know-How, (iv) Safety Switch Licensed Know-How, (v) [***] Licensed Know-How, and (vi) Initial Tech Transfer Package, including making relevant personnel available to BioNTech, which may include [***]. Autolus shall, if requested [***], make no fewer than [***] FTEs, who shall be scientific or technical personnel of Autolus, available to BioNTech for [***]. For the avoidance of doubt, [***] the Initial Tech Transfer Package, the [***] Licensed Know-How, [***] Licensed Know-How, Activity Enhancement Licensed Know-How, Safety Switch Licensed Know-How or [***] Licensed Know-How.

5.9 **Development and Commercialization.** BioNTech is responsible for conducting, at its sole expense, the Development and Commercialization of [***] Licensed Products in the Field in the Territory.

5.10 [***] **Licensed Product Diligence.** BioNTech shall use Commercially Reasonable Efforts: to (a) [***], and (b) [***].

5.11 **Reporting Obligations.** BioNTech shall, within [***] after [***] until [***], provide Autolus with a written report summarizing, [***] in respect of the [***] Licensed Binder, the [***] Licensed Binder, and [***] Licensed Products. All information and reports provided to Autolus pursuant to this Section 5.11 shall be deemed the Confidential Information of BioNTech hereunder.

5.12 **Regulatory Matters.**

(a) **Regulatory Filings.** As between the Parties, BioNTech has the sole responsibility for preparing and submitting all Regulatory Filings and all Drug Approval Applications for all [***] Licensed Products in the Field in each country within the Territory. At the request of BioNTech [***], Autolus shall provide such assistance as is [***] for BioNTech to prepare and submit Regulatory Filings for [***] Licensed Products in the Field. BioNTech shall own and maintain all Regulatory Filings and Regulatory Approvals for [***] Licensed Products in the Field. [***], BioNTech shall notify Autolus of [***].

(b) **Adverse Event Reporting.** Within [***], the Parties will discuss whether a pharmacovigilance agreement, governing each Party's respective obligations with respect to adverse event reporting, monitoring, maintenance of safety databases and submissions to Regulatory Authorities and other similar obligations with respect to [***] Licensed Products [***]. If a [***], then within [***], the Parties shall [***]. Such [***]. Notwithstanding any other provisions of this Agreement, if [***], or [***] Licensed Product, or [***], then such Party shall provide the other Party with [***].

(c) **Recalls.** As between the Parties, BioNTech has the sole right to determine whether and how to implement a recall or other market withdrawal of a [***] Licensed Product in the Field in each country within the Territory.

6. Technologies Options

6.1 **Non-Exclusive License Grant.** Subject to the terms and conditions of this Agreement and during the applicable Technologies Option Period, Autolus hereby grants to BioNTech a non-exclusive, non-transferable, limited, non-sublicensable (other than to Third Party Evaluators) license under the Technologies Option IP for BioNTech's internal research purposes to evaluate whether BioNTech wishes to exercise a Technologies Option in respect of all or part of the Technologies Option Technology ("**Evaluation**"). For the avoidance of doubt, BioNTech shall conduct the Evaluation solely in relation to (a) Activity Enhancement Licensed Products in the Field (and, with respect to Other AE Licensed Products, solely with respect to a Target that has been pre-cleared pursuant to Section 6.4), (b) [***] Licensed Products in the Field, (c) Safety Switch Licensed Products in the Safety Switch Field, and (d) [***] Licensed Products in the [***] Field. Such license shall commence on the Effective Date and shall expire: (i) in respect to the [***] Option, on the [***] (the "[***] **Option Period**"), (ii) in respect to the [***] Option, on the [***] (the "[***] **Option Period**"), and (iii) in respect to each Module Option, on the [***] (the "**Module Option Period**"). BioNTech shall ensure that any sublicenses of the rights under this Section 6.1 to Third Party Evaluators shall be in writing and be consistent with the applicable terms and conditions of this Agreement. BioNTech shall remain responsible for the performance of all of its Third Party Evaluators to the same extent as if such activities were conducted by BioNTech.

6.2 Transfer of Technologies Option Technology.

(a) [***], Autolus shall transfer to BioNTech such of the Technologies Option Technology, and in such quantities, as set out in Schedule 6.2 ("**Transferred Materials**"). BioNTech shall use the Transferred Materials and all Technologies Option Technology solely for the purposes of the Evaluation and for no other purpose. The Transferred Materials and all tangible embodiments of the Technologies Option Technology shall (i) at all times remain solely under the control of BioNTech or one of its Affiliates or Third Party Evaluators, (ii) be used in compliance with Applicable Laws, (iii) not be used by or delivered by BioNTech to or for the benefit of any Third Party, other than a Third Party Evaluator, without the prior written consent of Autolus, and (iv) not be used by BioNTech for any research or testing involving human subjects.

(b) BioNTech, its Affiliates, and its Third Party Evaluators shall not attempt to reverse engineer, design around, deconstruct or in any way determine the structure or composition of the Transferred Materials without the prior written consent of Autolus, but it is acknowledged that as part of the Evaluation, BioNTech may [***]. BioNTech shall [***] and nothing in this Agreement restricts [***]. Autolus shall [***] and nothing in this Agreement restricts [***], unless and until [***]. BioNTech shall [***] in writing, providing [***]. BioNTech [***]. If any [***], neither Party shall be permitted to: (i) [***]; or (ii) [***], in each case (i) and (ii), unless and until a Technologies License Agreement regarding the Technologies Option Technology to which such [***] relates is executed, whereupon the terms of such Technologies License Agreement shall govern the Parties rights to use and Exploit [***].

(c) The Transferred Materials supplied to BioNTech are for experimental use only and are provided "as is" with no warranties of any kind, express or implied, including any warranty of merchantability or fitness for a particular purpose. Save as set forth in Article 15, the Technologies Option Technology supplied to BioNTech are for experimental use only and are provided "as is" with no warranties of any kind, express or implied, including any warranty of merchantability or fitness for a particular purpose. To the extent the Transferred Materials comprise cell lines, [***].

(d) BioNTech shall provide Autolus with [***] updates on [***]. Each such update will be provided [***], and BioNTech shall [***].

(e) When BioNTech has completed the Evaluation, following the expiry of the Technologies Option Period without a Technologies License Agreement having been entered into,

BioNTech shall [***] return to Autolus or destroy, at Autolus's instruction, any remaining Transferred Materials and cease all use of the Technologies Option Technology.

6.3 **Options.** Autolus grants to BioNTech, with effect from the Effective Date, the option (which is an exclusive option, solely with respect to (1) the [***] Option, (2) the [***] Option and (3) the option for a Co-Exclusive license in respect of the In Vivo AE Licensed Products), during the Technologies Option Period, to receive, in any combination, one or more of the following licenses, which (i) with respect to the [***] Option is solely exercisable in respect of [***], (ii) with respect to the [***] Option is solely exercisable in respect of [***], and (iii) with respect to each Module Option is exercisable on a Target-by-Target basis in respect of a specified Target, without a cap on the number of times that BioNTech may exercise a Module Option:

(a) (i) an exclusive, payment-bearing, license under the [***] Licensed IP (1) to Develop the [***] Licensed Binder and the [***] Licensed Binder in connection with a [***] Licensed Product, and (2) to Exploit [***] Licensed Products directed to [***], in each case of (1) and (2), in the [***] Field, (ii) a non-exclusive, non-transferable, limited, non-sublicensable (other than to Third Party Evaluators) license under the [***] Licensed IP to research and Develop (only up to and including [***]) a CAR-T Cell Therapy *provided* that (A) [***], and (B) [***]; *provided further* that [***] and (iii) a non-exclusive license under the [***] Licensed IP to Exploit [***] in conjunction with one or more [***] Licensed Products in the [***] Field (the “[***] **Option**”),

(b) (i) an exclusive, payment-bearing, license under the [***] Licensed IP (1) to Develop the [***] Licensed Binder in connection with a [***] Licensed Product, and (2) to Exploit [***] Licensed Products in the Field, and (ii) a non-exclusive, non-transferable, limited, non-sublicensable (other than to Third Party Evaluators) license under the [***] Licensed IP to research and Develop (only up to and including [***]) a CAR-T Cell Therapy *provided* that (A) [***], and (B) [***]; *provided further* that [***] (the “[***] **Option**”),

(c) a non-exclusive, payment-bearing, license under the Safety Switch Licensed IP to Exploit Safety Switch Licensed Products directed to such specified Target, in the Safety Switch Field (the “[***] **Safety Switch Option**”), and

(d) a Co-Exclusive, payment-bearing license under the Activity Enhancement Licensed IP to Exploit Activity Enhancement Licensed Products that express In Vivo any Activity Enhancement Licensed Technology (“**In Vivo AE Licensed Products**”) and are directed to such specified Target in the Field, and

(e) a non-exclusive, payment-bearing license under the Activity Enhancement Licensed IP to Exploit Activity Enhancement Licensed Products that do not express In Vivo any Activity Enhancement Licensed Technology (“**Other AE Licensed Products**”) and are directed to such specified Target in the Field, *provided* that such non-exclusive license in relation to a given Target is not effective unless and until such Target has been deemed Available pursuant to the gatekeeping procedure in Section 6.4. For clarity, if a specified Target is not Available then BioNTech may still exercise the Activity Enhancement Option on such Target to practice the Co-Exclusive license granted in relation to In Vivo AE Licensed Products.

The licenses for which BioNTech has an option under this Section 6.3 and that will be granted under the applicable Technologies License Agreement following BioNTech's exercise of a Technologies Option, if any, may be sublicensed on the terms set forth in Section 2.2 of the applicable Technologies License Agreement.

If BioNTech, its Affiliates or Sublicensees wishes to Exploit any [***] Licensed Product in combination with a CAR-T Cell Therapy that [***] (the “[***] **Autolus [***] CAR-T**”), then prior to [***], BioNTech shall provide Autolus with prior written notice and grants, and shall procure the grant of, to Autolus, for a period of [***] after receipt of such notice, a right of first negotiation to, [***], negotiate and enter into an agreement with BioNTech, its Affiliate or Sublicensee (as applicable) for Autolus or its Affiliate to be BioNTech's partner for such combination therapy, whereby such [***] Licensed Product

would be used in combination with such Autolus [***] CAR-T. Prior to or during such [***] period, BioNTech, its Affiliates and Sublicensees shall [***].

If BioNTech, its Affiliates or Sublicensees wishes to Exploit any [***] Licensed Product in combination with a CAR-T Cell Therapy that [***] (the “**Autolus [***] CAR-T**”), then prior to [***], BioNTech shall provide Autolus with prior written notice and grants, and shall procure the grant of, to Autolus, for a period of [***] after receipt of such notice, a right of first negotiation to, [***], negotiate and enter into an agreement with BioNTech, its Affiliate or Sublicensee (as applicable) for Autolus or its Affiliate to be BioNTech’s partner for such combination therapy, whereby such [***] Licensed Product would be used in combination with such Autolus [***] CAR-T. Prior to or during such [***] period, BioNTech, its Affiliates and Sublicensees shall [***].

6.4 Gatekeeping for Other AE Licensed Products.

(a) **Appointment.** The Parties shall, within [***], appoint a Gatekeeper. The fees and expenses of the Gatekeeper’s responsibilities under this Agreement shall be borne by [***]. For the avoidance of doubt, no gatekeeping procedure is required in relation to any Activity Enhancement Licensed Product other than Other AE Licensed Products.

(b) **Nomination of Targets.** If BioNTech wishes to conduct the Evaluation or exercise its Activity Enhancement Option, in each case, for Other AE Licensed Products in relation to a given Target, BioNTech must first clear such Target pursuant to the remainder of this Section 6.4(b). [***], BioNTech may provide Autolus with a written request that Autolus provide the Gatekeeper with a complete, accurate and then-current list of Targets that are not Available (“**Nomination Notice**”). Within [***] after BioNTech provides Autolus with such Nomination Notice, (i) Autolus shall provide the Gatekeeper with a complete, accurate and then-current list of Targets that are not Available and (ii) BioNTech shall provide the Gatekeeper with a list of [***] Targets that BioNTech wishes to nominate as a Target for which BioNTech may commence its Evaluation or exercise its Activity Enhancement Option, in each case, for Other AE Licensed Products directed to such specified Target (each a “**Nominated Target**”). To identify a Target as a Nominated Target, BioNTech shall provide the Gatekeeper with a confidential written description of each Nominated Target, including the name, aliases, and UniProt/SwissProt database identifier for such Nominated Target. Within [***] following Gatekeeper’s receipt of both Autolus’s list of Targets that are not Available and BioNTech’s list of Nominated Targets, the Gatekeeper shall notify BioNTech in writing whether or not each Nominated Target is Available (as defined below) (an “**Availability Notice**”). The Parties hereby acknowledge and agree that a Nominated Target shall be “**Available**” unless [***]. Within [***] after BioNTech’s receipt of an Availability Notice, BioNTech may (A) [***], (B) [***], or (C) [***]. The Gatekeeper shall not disclose the identity of a Nominated Target to Autolus unless it is designated as a Reserved Target or the identity of any Targets that Autolus has provided to the Gatekeeper unless it is a Nominated Target. For clarity, [***].

(c) **Reserved Targets.** If BioNTech desires to reserve an Available Nominated Target, then BioNTech shall notify both Autolus and the Gatekeeper in writing of the identity of such Nominated Target within [***] after BioNTech’s receipt of an Availability Notice, including the name, aliases, and UniProt/SwissProt database identifier for such Nominated Target (a “**Reserved Target**”). Autolus shall not enter into an agreement with a Third Party for Other AE Licensed Products directed to such Reserved Target if such agreement would prejudice BioNTech’s option rights to such Reserved Target until the end of the Module Option Period. For clarity, [***]. During the Module Option Period, BioNTech may designate [***], and may [***]. For clarity, [***].

(d) **Restricted Targets.** Autolus may notify the Gatekeeper in writing of the identity of [***] Targets within [***] following the appointment of the Gatekeeper, including the name, aliases, and UniProt/SwissProt database identifier for such Target (each a “**Restricted Target**”). [***] during the Module Option Period, Autolus may provide the Gatekeeper with a confidential written description of any Targets that it wishes to substitute for any existing Restricted Targets, including the name, aliases, and UniProt/SwissProt database identifier for such Target (each a “**Nominated Restricted Target**”), and identify which of the existing Restricted Targets that it wishes to substitute for each Nominated Restricted Target (a “**Substitutability Notice**”). Within [***] following the Gatekeeper’s receipt of Autolus’s list of Nominated Restricted Targets, the Gatekeeper shall notify Autolus in writing whether or not each

Nominated Restricted Target is Substitutable (as defined below). The Parties hereby acknowledge and agree that a Nominated Restricted Target shall be “**Substitutable**” unless such Target (i) [***], or (ii) [***]. On notification to Autolus that a Nominated Restricted Target is Substitutable, the Gatekeeper shall replace the previously Restricted Target indicated in the applicable Substitutability Notice.

6.5 **Option Exercise.** BioNTech may notify Autolus in writing that it wishes to exercise any of the Technologies Options, identifying (a) precisely which Technologies Option Technology such Technologies Option will be exercised in relation to, including, where applicable, the relevant regulatable control module of the Safety Switch Licensed Technology, and module of the Activity Enhancement Licensed Technology, and (b) the identity of the applicable Target (which with respect to the [***] Option will be [***], and with respect to the [***] Option, will be [***]) (“**Technologies Option Exercise Notice**”). For clarity, with respect to any Activity Enhancement Option, with respect to an Other AE Licensed Product, such Target must either have been identified as being Available under Section 6.4(b) within the [***] prior to the date of delivery of such Technologies Option Exercise Notice or be a Reserved Target under Section 6.4(c). On receipt of such Technologies Option Exercise Notice, [***] shall, within [***], prepare the license agreement reflecting the details set out in such Technologies Option Exercise Notice, which shall be in the form set out in Schedule 6.5 (“**Technologies License Agreement**”). The Parties shall [***] execute the Technologies License Agreement after it has been finalized, and the Technologies Option Exercise Fee for the applicable Technology Option shall be paid in accordance with Section 6.6. BioNTech may exercise any Technologies Option on one or more occasions during the applicable Technologies Option Period. For the avoidance of doubt, [***] only one Technologies Option Exercise Fee will have to be paid for each such [***].

6.6 **Option Exercise Fee.** [***], Autolus shall submit to BioNTech an invoice for the applicable Technologies Option exercise fee (if any) set out in the below table (“**Technologies Option Exercise Fee**”), *provided* that, if a particular Technologies Option is exercised in respect of [***] of the [***] Option, [***] Option, any Safety Switch Licensed Technology module, and any Activity Enhancement Licensed Technology module in respect of the same Target, then the applicable Technologies Option Exercise Fee shall be [***]: (a) [***], and (b) [***] (the “**Technologies Option Exercise Fee Cap**”).

	Activity Enhancement Option (per module)	Safety Switch Option (per regulatable control module)	[***] Option	[***] Option
Technologies Option Exercise Fee	[***]	[***]	[***]	[***]

[***].

6.7 Failure to Exercise Technologies Option.

(a) [***]. On expiry of the [***] Option Period, the [***] Option shall expire without any further action required on the part of either Party, and Autolus will have no further obligations to BioNTech under this Article 6 with respect to [***] and, except to the extent it would conflict with the terms of any Technologies License Agreement, Autolus, at its sole discretion, may negotiate with any Third Party a transaction, including an exclusive license, in respect of the [***] Licensed IP, and all rights relating thereto, without reference to BioNTech. BioNTech shall [***] destroy

any data, results, and information generated by it pursuant to the Evaluation with respect to the expired [***] Option, other than data, results, and information pertaining to [***].

(b) [***]. On expiry of the [***] Option Period, the [***] Option shall expire without any further action required on the part of either Party, and Autolus will have no further obligations to BioNTech under this Article 6 with respect to [***] and, except to the extent it would conflict with the terms of any Technologies License Agreement, Autolus, at its sole discretion, may negotiate with any Third Party a transaction, including an exclusive license, in respect of the [***] Licensed IP, and all rights relating thereto, without reference to BioNTech. BioNTech shall [***] destroy any data, results, and information generated by it pursuant to the Evaluation with respect to the expired [***] Option, other than data, results, and information pertaining to [***].

(c) **Module.** On expiry of the Module Option Period, each Module Option shall expire without any further action required on the part of either Party, and Autolus will have no further obligations to BioNTech under this Article 6 with respect to the Activity Enhancement Licensed Technology and the Safety Switch Licensed Technology and, except to the extent it would conflict with the terms of any Technologies License Agreement, Autolus, at its sole discretion, may negotiate with any Third Party a transaction, including an exclusive license, in respect of the Activity Enhancement Licensed IP and Safety Switch Licensed IP, and all rights relating thereto, without reference to BioNTech. BioNTech shall [***] destroy any data, results, and information generated by it pursuant to the Evaluation with respect to the expired Module Option, other than data, results, and information pertaining to [***].

7. Obe-Cel Product

7.1 Reporting Obligations.

(a) Autolus shall, within [***], and on [***] thereafter, until [***], provide BioNTech with a written report [***], Development activities conducted during [***] in respect of the Obe-cel Product for all Indications other than [***]. All information and reports provided to BioNTech pursuant to this Section 7.1 shall be treated as Confidential Information of Autolus hereunder.

(b) Autolus shall, at the end of [***] following [***], provide BioNTech with [***] of the Commercialization of Obe-cel Product in [***] in such [***], including [***]; *provided*, that upon [***], the reports provided under this Section 7.1(b) will be provided [***] and will be limited to [***]; *provided*, further, [***].

(c) At BioNTech's request, within [***] following BioNTech's receipt of the reports detailed in Section 7.1(a) or Section 7.1(b), the Parties shall meet to discuss the reports and the progress of the activities detailed in such reports, as well as the anticipated activities to be undertaken by Autolus during the forthcoming [***] period.

7.2 **Potential Support.** The Parties may discuss potential commercial support which could be provided by BioNTech in support of the Commercialization of Obe-cel Product. For clarity, unless BioNTech and Autolus subsequently enter into an exclusivity agreement in relation to the Commercialization of Obe-cel Product (which for clarity, neither Party is under an obligation to enter into), Autolus may discuss and conclude agreements with Third Parties for the Commercialization of Obe-cel Product without any obligation to notify BioNTech.

7.3 **Upfront Payment.** As partial consideration for the Obe-cel Revenue Interest, within [***] after the receipt of an invoice issued by Autolus on or after the Effective Date BioNTech shall pay to Autolus the non-refundable, non-creditable sum of Forty Million Dollars (\$40,000,000) (the "**Upfront Payment**").

7.4 Obe-cel Milestones.

(a) As partial consideration for the rights granted under this Agreement, BioNTech may, at its sole discretion, elect to pay to Autolus the non-refundable, non-creditable milestone payments upon the achievement of each of the following milestone events by the Obe-cel Product (whether by or on

behalf of Autolus, its Affiliates or Autolus Licensees). Each milestone will be payable a maximum of once. For clarity, [***]:

Milestone Event	Milestone Payment
[***] (“Obe-cel Milestone 1”)	[***]
[***] (“Obe-cel Milestone 2”)	[***]
[***] (“Obe-cel Milestone 3”)	[***]
Total	\$100,000,000

(b) **Notice and Payment.** Autolus shall notify BioNTech in writing within [***] after the first achievement of any milestone event set forth in this Section 7.4 by or on behalf of Autolus, its Affiliates or Autolus Licensees. If BioNTech elects to make a milestone payment in respect of the achievement of such milestone event, BioNTech shall notify Autolus within [***] following receipt of Autolus’s notification of the first achievement of such milestone event, and Autolus shall send to BioNTech the invoice for the appropriate milestone payment, which shall be paid by BioNTech within [***] of receipt of such invoice. For clarity, [***].

7.5 **Obe-cel Revenue Interest Payments.** As partial consideration for the receipt by Autolus of the Upfront Payment, on a country-by-country basis in the Territory during the Obe-cel Revenue Interest Term in such country, Autolus shall pay to BioNTech an amount equal to [***] of annual Net Sales of Obe-cel Products (the “**Initial Obe-cel Revenue Interest Percentage**”). As consideration for the receipt by Autolus of milestone payments under Section 7.4, the Initial Obe-cel Revenue Interest Percentage shall be increased as set forth in the table below upon Autolus’s receipt of the applicable milestone payment under Section 7.4 (the Initial Obe-cel Revenue Interest Percentage and any Additional Revenue Interest Percentage, collectively the “**Obe-cel Revenue Interest**”).

Milestone Event	Additional Revenue Interest Percentage
[***]	[***]
[***]	[***]
[***]	[***]

By way of example, [***].

7.6 **Obe-cel Product Diligence.** Autolus shall use Commercially Reasonable Efforts: to (a) [***], and (b) [***].

8. [*]**

8.1 [***] hereby grants [***] a [***] with [***] granting [***] and [***] if [***] intends (a) to [***], or to [***], or (b) to [***] related to [***] ((a) and (b) constituting an “[***]”) for a period of [***] commencing on the Effective Date (the “[***]”), subject to and as further set out in Section 8.3. Notwithstanding the foregoing, the rights in this Section 8.1 do not apply to [***]. For clarity, this Section 8.1 remains in full force and effect following [***]. For further clarity, [***].

8.2 [***] shall, within [***] after the Effective Date, deliver to [***], all information and data [***] in relation to the [***]. Upon [***] request, [***] shall deliver to [***] (to the extent such [***]) in the formats such information and data are held by [***] at the time of such request. [***] will provide the JSC with updates on the progress of [***] in relation to [***], every [***] during the [***]. During [***] shall on [***] reasonable request (a) request from [***] in relation to [***] which has not been provided to [***], (b) [***] facilitate access for [***] to the [***], and (c) [***] provide [***]. To the extent that any data to be provided under this Section 8.2 constitutes Personal Data, [***] shall only be obliged to deliver such Personal Data to [***] to the extent to which it can be delivered in compliance with Applicable Data Protection Law. If the current formats are not compatible with the transfer of such information and data to [***] in compliance with Applicable Data Protection Law, then [***] shall use [***] (i) to obtain such information and data in an anonymized or other format that (1) can be transferred to [***] and (2) results in the applicable information and data no longer constituting Personal Data under Applicable Data Protection Law, or (ii) to facilitate an appropriate data transfer agreement under which such data can be provided to [***] in compliance with Applicable Data Protection Law, *provided* that if [***].

8.3 If, during the [***] is contemplating [***], then, prior to [***] (an “[***]”), [***] shall provide [***] with prior written notice and all material information and data relating to [***] then in its possession (to the extent not previously provided pursuant to Section 8.2) and for a period of [***] after receipt of such notice and information, [***] has a [***], and during such [***] would not [***].

8.4 If the Parties [***] may engage [***] with a [***] or enter into [***] with a [***].

9. Financial Provisions

9.1 **License Payment.** As partial consideration for the rights granted under this Agreement with respect to the [***] Licensed IP and the Technologies Option Technology, within [***] after the receipt of an invoice issued by Autolus on or after the Effective Date BioNTech shall pay to Autolus the non-refundable, non-creditable sum of Ten Million Dollars (\$10,000,000).

9.2 [***] Royalty Payments.

(a) **Royalty Rate.** In partial consideration of the license granted to BioNTech pursuant to Section 5.1, on a [***] Licensed Product-by-[***] Licensed Product and country-by-country basis, during the applicable [***] Royalty Term for such [***] Licensed Product and such country, BioNTech shall pay to Autolus royalties on Net Sales of such [***] Licensed Product in such country at a rate of [***], as may be increased pursuant to Section 9.2(c) and as may be decreased pursuant to Section 9.2(b) (“[***] Royalties”).

(b) Royalty Rate Reductions.

(i) [***]. For any period during the [***] Royalty Term in which [***] (A) [***], the royalty rate with respect to Net Sales of such [***] Licensed Product for the remainder of the applicable [***] Royalty Term shall be reduced by [***], and (B) [***], the royalty rate with respect to Net Sales of such [***] Licensed Product for the remainder of the applicable [***] Royalty Term shall be reduced by [***]. The Parties [***].

(ii) **Biosimilar Reduction.** On a country-by-country and [***] Licensed Product-by-[***] Licensed Product basis, during the [***] Royalty Term for such [***] Licensed Product in such country, if [***], the [***] of such [***] Licensed Product in such country [***], then, thereafter, the [***] Royalties payable with respect to [***] of such [***] Licensed Product in such country will be reduced by percentage set forth in the following table.

[***]	Royalty Reduction
[***]	[***]
[***]	[***]

(iii) **Third Party Intellectual Property.** If BioNTech or one of its Affiliates obtains a license to [***] owned or otherwise controlled by a Third Party that [***], and [***], then, thereafter, BioNTech may deduct [***] of the [***] paid by BioNTech to the applicable Third Party ([***) as an offset to the royalties payable by BioNTech to Autolus for the applicable [***] Licensed Product with respect to [***].

(iv) **IRA Reduction.** If a [***] Licensed Product is designated as a “selected drug” by the Secretary of the U.S. Department of Health and Human Services, and BioNTech is required to negotiate a maximum fair price that shall apply to sales of such [***] Licensed Product during the price applicability period as specified in the Inflation Reduction Act, then the royalties payable with respect to all sales of such [***] Licensed Product in the United States shall be reduced by [***].

(v) **Royalty Floor.** Save as provided in [***], when royalties may be reduced to [***], on a [***] Licensed Product-by-[***] Licensed Product and country-by-country basis, in no event will the aggregate amount of [***] Royalties due to Autolus for such [***] Licensed Product in such country in a Calendar Quarter during the applicable [***] Royalty Term be reduced pursuant to this Section 9.2(b) by more than [***] of the amount that would otherwise be due to Autolus in the absence of such reductions *provided* that BioNTech may carry over and apply any such royalty reductions that are incurred or accrued in a Calendar Quarter and are not deducted in such Calendar Quarter, to any subsequent Calendar Quarters (subject to the floor in this Section 9.2(b)).

(c) **Royalty Rate Increase.** Notwithstanding Section 9.2(a), but subject to Section 9.2(b) if BioNTech, its Affiliates or Sublicensee Commercializes a [***] Licensed Product and, during the applicable [***] Royalty Term for such [***] Licensed Product, Autolus, its Affiliates or Autolus Licensees has obtained or does obtain Regulatory Approval for a product containing a [***] Licensed Binder and/or a [***] Licensed Binder in both the same Indication and in the same country as such [***] Licensed Product (“[***] **Competing Product**”), then, on a [***] Licensed Product-by-[***] Licensed Product basis and country-by-country basis, the royalty rate in respect of such [***] Licensed Product in such Indication in such countries shall be increased to [***] from First Commercial Sale of the [***] Competing Product during any Calendar Quarter in which sales of the [***] Competing Product in such Indication and country are made.

9.3 [*] Milestone Payments.**

(a) In partial consideration of the rights granted by Autolus to BioNTech hereunder and subject to the terms and conditions set forth in this Agreement, BioNTech shall pay to Autolus on a [***] Licensed Product-by-[***] Licensed Product basis, the non-refundable, non-creditable milestone payments upon the first achievement of each of the following milestone events for each [***] Licensed Product to achieve such milestone event (whether by or on behalf of BioNTech, its Affiliates or Sublicensees). Each milestone will be payable a maximum of once for a given [***] Licensed Product. For clarity, [***]:

Milestone Number	Milestone Event	Milestone Payment
1	[***]	[***]
2	[***]	[***]
3	[***]	[***]
4	[***]	[***]
5	[***]	[***]
Total Per [***] Licensed Product		\$32,000,000

(b) **Notice and Payment.** BioNTech shall notify Autolus in writing within [***] after the first achievement of any milestone event set forth in this Section 9.3 by or on behalf of BioNTech, its Affiliates or Sublicensees. Based on this notice, Autolus shall then issue and send to BioNTech the invoice for the appropriate milestone payment, which shall be paid by BioNTech within [***] of receipt of such invoice.

(c) **Skipped Milestone Event.** If any of the [***] milestones set out in Section 9.3(a) is skipped for any reason, then such skipped milestone shall become payable on the achievement of the next milestone to be achieved, as if both the following milestone and the skipped milestone had been achieved simultaneously, but the [***] milestones are payable only as and when achieved. By way of example, if [***] is achieved, and then [***] is achieved without [***] having been achieved, then the milestone payments in respect of both [***] and [***] would become payable upon the achievement of [***]. If [***] is achieved before [***] have been achieved, then upon the achievement of [***] each of [***] will be payable to the extent not already paid. However, if [***].

9.4 **Cap on Option Exercise and Milestone Payments.** Notwithstanding the terms of this Article 9 or the terms of any Technologies License Agreement, the total amount payable by BioNTech to Autolus for all milestone payments and Technologies Option Exercise Fees under this Agreement and all Technologies License Agreements shall not exceed [***]. For the avoidance of doubt, this cap does not apply to royalty payments.

9.5 **Existing Third Party Payments.** Autolus is solely responsible for any payments owed to any Third Parties under the Upstream License Agreements and for any payments owed under the Intra-Group License.

10. Reports and Payment Terms

10.1 Reports; Timing of Payment and Royalty Statements.

(a) The Obe-cel Revenue Interest and [***] Royalties shall accrue at the time the payment for the sale of the applicable product is [***]. For each [***] during the Obe-cel Revenue Interest Term and [***] Royalty Term the Paying Party shall send to the Receiving Party within [***] a statement of [***]. Where there are Net Sales of Obe-cel Product or [***] Licensed Product other than [***], the Paying Party shall also provide details of [***]. The Selling Party shall procure that the foregoing information is obtained from any Autolus Licensee with respect to Obe-cel Product or Sublicensee with respect to [***] Product, as applicable. Each Party shall [***] require any Autolus Licensee (in the case of Autolus) and Sublicensee (in the case of BioNTech) to provide such statement within [***] after the end of such [***]. Royalty and revenue interest obligations that have accrued during a particular [***] shall be paid by the applicable Paying Party, on a [***] basis, within [***] after the end of such [***].

(b) BioNTech has no payment obligations to [***], but to enable Autolus to comply with its reporting obligations under [***], with effect on a [***] Licensed Product-by-[***] Licensed

Product basis from the First Commercial Sale of such [***] Licensed Product and throughout the remainder of the [***] Royalty Term for such [***] Licensed Product, within [***] following [***], BioNTech shall provide Autolus with a written report showing [***].

10.2 Mode of Payment and Currency. All payments hereunder shall be made by deposit of Dollars in the requisite amount to such bank account as the recipient may from time to time designate by written notice to the Paying Party, *provided* that such bank account is located in the European Union, the United Kingdom, or the United States. With respect to sales not denominated in Dollars, the Paying Party shall convert applicable sales in foreign currency into Dollars by using the then-current and reasonable standard exchange rate methodology applied to its external reporting. Based on the resulting sales in Dollars, the Paying Party shall calculate the applicable Obe-cel Revenue Interest or [***] Royalties.

10.3 Late Payments. If either Party fails to pay any undisputed payment under this Agreement by the date when such payment is due, then, without limiting any other right or remedy of the other Party, such late payment shall be paid together with interest thereon at an annual rate [***], from the date on which such payment was originally due until the date of payment (*provided*, that, such rate shall not exceed the rate permissible under Applicable Law).

10.4 Financial Records. (a) Autolus shall, and shall cause its Affiliates and Autolus Licensees to, keep complete and accurate financial books and records pertaining to the Exploitation of Obe-cel Products, and (b) BioNTech shall, and shall cause its Affiliates and Sublicensees to, keep complete and accurate financial books and records pertaining to the Exploitation of [***] Licensed Products, in each case ((a) and (b)) in sufficient detail to calculate all amounts payable hereunder with respect thereto and to verify compliance with its obligations under this Agreement. Such books and records shall be retained by the Parties and their Affiliates and, Autolus Licensees and Sublicensees (as applicable), until [***] after the end of the Calendar Year to which such books and records pertain.

10.5 Audit Rights.

(a) Either Party (the “**Auditing Party**”) may, upon written request to the other Party (the “**Audited Party**”), cause an internationally recognized independent accounting firm (which is reasonably acceptable to the Audited Party) (the “**Auditor**”) to inspect the relevant records of the Audited Party or its Affiliates to verify the royalties or revenue interest payable by such Audited Party under this Agreement, and the related reports, statements and books of accounts, as applicable; *provided* that, the Auditor may only inspect the relevant books and records of the Audited Party to verify sums payable under this Agreement by the Audited Party with respect to the [***] prior to the [***] in which such inspection request is made. Before beginning its audit, the Auditor will execute an undertaking acceptable to the Audited Party by which the Auditor shall agree to keep confidential all Confidential Information reviewed during such audit. The Auditor will disclose to the Auditing Party only its conclusions regarding any payments owed under this Agreement. On written request by Autolus, following a written request to Autolus by [***] to audit Autolus in accordance with [***], BioNTech shall, [***], provide to Autolus [***], *provided* that the foregoing obligations shall expire [***].

(b) The Audited Party shall make its relevant records available for inspection by such Auditor during regular business hours at such place or places where such records are customarily kept, upon receipt of reasonable advance notice from the Auditing Party. The records shall be reviewed solely to verify the accuracy of the Audited Party’s payments under this Agreement. The Auditing Party shall not exercise such inspection right more than once in any [***] and not more frequently than once with respect to records covering any specific period of time. The Auditing Party shall hold in strict confidence all Confidential Information received and all Confidential Information learned in the course of any audit or inspection, except to the extent necessary to enforce its rights under this Agreement or to the extent required to comply with any law, regulation or judicial order.

(c) If the final result of the inspection reveals an undisputed underpayment or overpayment by the Audited Party, then the underpaid or overpaid amount shall be settled [***].

(d) The Auditing Party shall pay for the fees and expenses of the Auditor, except that (i) BioNTech shall pay for such fees with respect to audits initiated by Autolus if BioNTech is found to

have underpaid Autolus by more than [***] of the amount that should have been paid for the audited period and (ii) Autolus shall pay for such fees with respect to audits initiated by BioNTech if Autolus is found to have underpaid BioNTech by more than [***] of the amount that should have been paid for the audited period.

10.6 Taxes.

(a) Sales Tax.

(i) All payments and other consideration under this Agreement are stated exclusive of Sales Tax. If any Sales Tax is chargeable in respect of any supply made by Autolus to BioNTech pursuant to this Agreement and Autolus, or any Affiliate of it, is required to account for such Sales Tax to a tax authority, BioNTech shall pay to Autolus an amount equal to such Sales Tax in addition to the payment or other consideration in respect of that supply. Such Sales Tax shall be payable at the same time as such payment or other consideration is due or otherwise required to be provided and Autolus, where applicable, shall provide BioNTech with a valid Sales Tax invoice. If any Sales Tax is chargeable in respect of any supply made by BioNTech to Autolus pursuant to this Agreement and BioNTech, or any Affiliate of it, is required to account for such Sales Tax to a tax authority, Autolus shall pay to BioNTech an amount equal to such Sales Tax in addition to the payment or other consideration in respect of that supply. Such Sales Tax shall be payable at the same time as such payment or other consideration is due or otherwise required to be provided and BioNTech, where applicable, shall provide Autolus with a valid Sales Tax invoice.

(ii) Where a Party is required under this Agreement to indemnify, pay or otherwise reimburse an amount in respect of any liability, cost, charge or expense incurred by another Party, the payor shall not be required to indemnify, pay or reimburse any amount in respect of Sales Tax which is recoverable (whether by way or repayment, credit or set off) by the payee (or any Affiliate of it), subject to the payee (or such Affiliate) using [***] to recover such Sales Tax.

(b) Withholding Tax.

(i) All sums payable and other consideration provided under this Agreement shall be paid or provided by the Party making the payment or providing the consideration (the "**Paying Party**") without any withholding or deduction for, or on account of, any Taxes, except for taxes that are required to be withheld or deducted by Applicable Law.

(ii) If any deductions or withholdings for or on account of Tax are required to be made by Applicable Law in respect of any amounts payable or other consideration provided under this Agreement, the Paying Party shall withhold or deduct an amount equal to any such Tax, account for such Tax to the relevant tax authority within the time required by Applicable Law and provide to the party entitled to receive such amount or other consideration (the "**Receiving Party**") reasonable evidence of the payment of such Tax, including official receipts (where available), and such withheld or deducted Taxes shall be treated for all purposes of this Agreement as having been paid to the Receiving Party.

(iii) The Parties shall, in respect of the payment or other consideration in question (other than any payment of interest), cooperate and take all steps reasonably and lawfully available to them, including completing such procedural formalities as are necessary, to establish the Receiving Party's entitlement to any exemption from, or diminution in the amount of, any relevant deduction or withholding for or on account of Tax and to enable the Paying Party to obtain any necessary authorization to make payment or provide consideration without, or subject to a reduced amount of, deduction or withholding for or on account of Tax (including, in each case and for the avoidance of doubt, in relation to any applicable exemption certificate) and to provide the Receiving Party with such assistance as is reasonably required to obtain a refund of, or credit with respect to, any such Tax required to be deducted or withheld.

(iv) If a Party takes any action (not required by the terms of this Agreement), including any assignment, transfer, sublicense, change of place of incorporation or tax residence, or a change of the place of business or other permanent establishment through which it receives the supplies

made under this Agreement or with which the performance of its obligations under this Agreement is effectively connected, which results in an obligation, or increased obligation, to withhold or deduct tax with respect to payments to be made or other consideration to be provided to the other Party pursuant to this Agreement, then [***].

(v) In the event that (i) a withholding tax deduction was omitted, (ii) an exemption certificate of the Receiving Party as required under the German anti-treaty-shopping rules for the Paying Party to abstain from a withholding obligation has become invalid, and (iii) it is detected after a payment to the Receiving Party that a withholding tax deduction should have been made under such rules in respect of such payment, the Paying Party may withhold such amount as ought to have been so withheld from subsequent payments under this Agreement, or the Receiving Party shall reimburse the Paying Party for such amounts [***]. In respect of any such subsequent deduction or reimbursement, any effect resulting from currency conversion is benefit or burden of Receiving Party as taxpayer and not borne by Paying Party. Each of the Paying Party and the Receiving Party shall notify the other Party [***] after becoming aware that an exemption certificate (that has reduced or eliminated any obligation to deduct or withhold an amount of, or in respect of, Tax, from any payment under this Agreement) has become invalid.

(vi) The Parties' assessment of currently Applicable Law is that [***].

(c) **Information and Assistance.** Each Party shall, [***] following a request in writing by the other Party [***], provide to that other Party (or any of its Affiliates) such information within its possession and assistance concerning the matters contemplated by this Agreement (including any matters contemplated by any MCSA and any Research and Development Collaboration Agreement referred to in Section 3.2) as the relevant Party may reasonably request in connection with its (or any Affiliate's) tax affairs (including in connection with any claim for research and development tax credits that such Party (or any of its Affiliates) may wish to make).

(d) **Customs.** Autolus shall provide to BioNTech any documents necessary for tax and customs clearance for the Transferred Materials in a format as required and specified by BioNTech. Any shipment of Transferred Materials by Autolus to BioNTech or its Affiliates must be announced [***] in advance at [***]. An invoice for customs purposes showing exact costs per shipped good must be provided. Shipments of Transferred Materials to BioNTech will be made [***] designated by BioNTech. Deviation must be discussed in advance with [***].

11. Intellectual Property Rights.

11.1 **Background Intellectual Property.** Except as expressly set forth herein, as between the Parties, each Party is and shall remain the owner of all intellectual property that it owned or otherwise controlled as of the Effective Date or that it develops, licenses, or otherwise acquires thereafter pursuant to activities independent of this Agreement (with respect to each Party, "**Background IP**").

11.2 Inventions.

(a) Save as provided in [***], as between the Parties, [***]. Save as provided in Section 11.2(b), [***].

(b) Notwithstanding Section 11.2(a), or any other provision to the contrary set forth in this Agreement, the terms of the MCSA, the Research and Development Collaboration Agreement and any [***], and any [***] shall govern ownership of inventions generated under such agreement.

11.3 Patent Prosecution and Maintenance of [***] Licensed Patents.

(a) [***] has the [***] right, but not the obligation, to prepare, file, prosecute and maintain the [***] Licensed Patents, at [***] sole cost and expense. [***] shall keep [***] reasonably informed of all steps with regard to the preparation, filing, prosecution, and maintenance of the [***] Licensed Patents. [***] shall provide [***] with a copy of [***] communications to and from the patent authorities regarding the [***] Licensed Patents, including drafts of [***] shall consider [***] reasonable

comments with respect to such drafts. Without limitation to the generality of the foregoing, [***] shall during the Term:

(i) on a [***] basis, keep [***] informed of [***] with respect to those [***] Licensed Patents that [***] (the “[***] Licensed Product-Specific Patents”), and the status of, filing, prosecution and maintenance activities therefor, including providing [***];

(ii) [***], give [***] (1) an opportunity to review and comment (for not less than [***]) on the proposed text of any papers related to the filing of [***] Licensed Product-Specific Patents, and (2) an opportunity to review and comment (for not less than [***]) on the proposed text of any papers related to prosecution of [***] Licensed Product-Specific Patents;

(iii) supply [***] with a copy of each such [***] Licensed Product-Specific Patent application as filed, together with notice of its filing date and serial number; and

(iv) provide copies of any papers, office actions and other [***] correspondence received related to the prosecution of such [***] Licensed Product-Specific Patents within [***] prior to the deadline for taking action with respect thereto.

(b) [***] agrees that, in consultation with [***] and at [***] request, [***] shall (i) prepare, file, prosecute, and maintain the [***] Licensed Patents in a manner that will generate one or more [***] Licensed Product-Specific Patents, and (ii) include any reasonable comments of [***] on all such potential filings of [***] pursuant to clause (i) of this sentence so as to generate a mutually agreeable filing; *provided, however*, that [***].

11.4 Enforcement of [***] Licensed Patents.

(a) **Notice.** If either Party knows or believes that an infringement, unauthorized use, misappropriation, ownership claim, threatened infringement or other similar activity by a Third Party exists or has occurred with respect to any [***] Licensed Patent, or if a Third Party claims that any [***] Licensed Patent is invalid or unenforceable, then such Party shall notify the other Party and provide it with all details that are known by such Party.

(b) **Right to Bring an Action.** As between the Parties, [***] has the [***] right, but not the obligation, to enforce and defend under its control, at its own expense, the [***] Licensed Patents (including the [***] Licensed Product-Specific Patents) where the putative infringing activity [***] (collectively a “**Competitive Infringement**”). Notwithstanding the foregoing, [***] shall not take any action in respect of any Competitive Infringement that [***], without the express written consent of [***]. [***] has the [***] right, but not the obligation, at its own expense, to enforce any other infringements of the [***] Licensed Patents. [***] also has the right to defend the [***] Licensed Patents where such defense arises outside the context of a Competitive Infringement. If the validity or enforceability of a [***] Licensed Patent is challenged in the course of a Competitive Infringement or any action that [***] is controlling, then [***] shall have the [***] right to control such challenge in accordance with Section 11.6.

(c) **Reasonable Assistance.** Upon request from the other Party, each Party shall provide reasonable assistance to the other Party to prosecute and to settle any enforcement or defense action under the control of the prosecuting Party in accordance with Section 11.4(b), including joining as a party to such action, providing access to relevant documents and other evidence and making its employees available, subject to [***]. If either Party is unable to initiate or prosecute an action without joinder of the other Party, then such Party will join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for such Party to initiate litigation under Section 11.4(b). Notwithstanding the foregoing, [***] shall not settle any Competitive Infringement in a manner that [***], without the express written consent of [***].

(d) **Recovery.** Any recovery realized as a result of such litigation described in this Section 11.4 (whether by way of settlement or otherwise) shall [***]. Any remainder after such reimbursement is made shall [***].

11.5 **Infringement Claims by Third Parties.** If the Exploitation of a [***] Licensed Product in the Territory pursuant to this Agreement results in, or may result in, any claim, suit, or proceeding by a Third Party alleging patent infringement by [***], then [***] has the [***] right, but not the obligation, to defend and control the defense of any such claim, suit, or proceeding at its own expense, using counsel of its own choice; *provided, however*, that the provisions of Section 11.4 shall govern the right of [***] to assert a counterclaim of infringement of any [***] Licensed Patent, and where the validity or enforceability of a [***] Licensed Patent is challenged in the course of such litigation, the provisions of Section 11.6 shall govern the right of [***] to defend such [***] Licensed Patent. [***] shall [***] notify [***] of any such claim, suit, or proceeding where the alleged patent infringement relates to [***], and keep [***] reasonably informed of all material developments in connection with any such claim, suit, or proceeding.

11.6 **Defense of [***] Licensed Patents.** Each Party shall [***] notify the other Party in writing of any alleged or threatened assertion by a Third Party of invalidity or unenforceability of any of the [***] Licensed Patents, in each case in the Territory and of which such Party becomes aware. As between the Parties, [***] shall have the [***] right, but not the obligation, to defend and control the defense of the validity and enforceability of the [***] Licensed Patents, at its sole cost and expense. [***] shall assist and cooperate with [***] as [***] may reasonably request from time to time, at [***] sole cost and expense, in connection with its activities set forth in this Section 11.6, including by being joined as a party plaintiff in such action or proceeding, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours. Where [***] exercises its right to control the defense of a challenge to the validity or enforceability of a [***] Licensed Patent in the course of a Competitive Infringement action or proceeding pursuant to Section 11.4, or a Third Party infringement action or proceeding pursuant to Section 11.5, the Parties shall fully consult and cooperate as regards the conduct of such action or proceeding. Notwithstanding the foregoing, [***] shall not settle the defense of a challenge to the validity or enforceability of a [***] Licensed Patent in the course of any Competitive Infringement action or proceeding pursuant to Section 11.4, or any Third Party infringement action or proceeding pursuant to Section 11.5, [***] without the express written consent of [***].

11.7 **UPC.** [***] has the [***] right to determine whether to opt in or opt out (and to opt in again) of the Unified Patent Court system with respect to the [***] Licensed Patents, and if requested by [***] shall [***], *provided* that [***].

11.8 **Patent Linkage.** As between the Parties, [***] shall have the [***] right, at its sole cost and expense, to obtain patent term extensions, supplementary protection certificates, and equivalents thereof with respect to any [***] Licensed Patent in any country in the Territory, *provided* that [***] shall [***].

12. Confidentiality

12.1 **Duty of Confidence.** Subject to the other provisions of this Article 12, all Confidential Information disclosed by or on behalf of a Party or any of its Affiliates (the “**Disclosing Party**”) under this Agreement will be maintained in confidence and otherwise safeguarded by the recipient Party and its Affiliates (“**Recipient Party**”) during the Term and for a period of [***] thereafter. Notwithstanding the foregoing, (a) [***] and any statement in respect of the Obe-cel Revenue Interest provided under Section 10.1 is the Confidential Information of Autolus, (b) any information and reports delivered under Section 5.11, any notice delivered under Section 9.3(b), any statement in respect of the [***] Royalties provided under Section 10.1, and any [***] is the Confidential Information of BioNTech, and (c) the terms of this Agreement are the Confidential Information of both Parties. The Recipient Party may only use the Confidential Information of the Disclosing Party for the purposes set forth in this Agreement. Subject to the other provisions of this Article 12, each Recipient Party shall hold as confidential such Confidential Information of the Disclosing Party or its Affiliates [***].

12.2 **Exceptions.** The obligations under this Article 12 shall not apply to any information to the extent that [***] such information:

(a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the Recipient Party;

(b) was known to, or was otherwise in the possession of, the Recipient Party prior to the time of disclosure by the Disclosing Party;

(c) is disclosed to the Recipient Party on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the Disclosing Party or a Third Party; or

(d) is independently developed by or on behalf of the Recipient Party, [***], without reference to the Confidential Information disclosed by the Disclosing Party under this Agreement.

Any combination of Confidential Information shall not be considered in the public domain or in the possession of the Recipient Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Recipient Party unless the combination and its principles are in the public domain or in the possession of the Recipient Party.

12.3 Authorized Disclosures. Each Recipient Party may disclose Confidential Information of the Disclosing Party as expressly permitted by this Agreement (including under Section 12.10), or if and to the extent such disclosure is necessary in the following instances:

(a) filing or prosecuting Know-How or Patents without breaching this Agreement;

(b) complying with applicable court orders, Applicable Laws, Applicable Data Protection Law, or the listing rules of any exchange on which such Recipient Party's securities (or the securities of its parent entity) are traded (subject to Section 12.5 with respect to any disclosure of the terms of this Agreement);

(c) in the case of BioNTech as the Recipient Party only, disclosure of such of Autolus's Confidential Information in Regulatory Filings that the Recipient Party has the right to file, or holds;

(d) in the case of BioNTech as the Recipient Party only, disclosure of such of Autolus's Confidential Information to BioNTech's Affiliates, licensees, sublicensees/Sublicensees (through multiple tiers), subcontractors, and other Third Party collaboration partners, and potential licensees, sublicensees/Sublicensees, subcontractors, and other Third Party collaboration partners, *provided*, that [***];

(e) disclosure to a Tax authority in connection with the Tax affairs or a reporting obligation of the Recipient Party;

(f) disclosure to such Recipient Party's directors, employees, [***] who have a need to know such information in order for the Recipient Party to exercise its rights or fulfill its obligations under this Agreement and [***];

(g) disclosure to (i) [***], and (ii) [***], *provided*, in each case, that [***], and *provided, further*, that [***]; and

(h) in the case of Autolus as the Recipient Party only, disclosure of (i) [***], and (ii) [***], in each case (i) and (ii) as reasonably required to enable Autolus and its Affiliates to comply with the terms of each Upstream License Agreement.

Notwithstanding the foregoing, and subject to Section 12.5 with respect to any disclosure of the terms of this Agreement, if the Recipient Party is required to disclose Confidential Information of the Disclosing Party in connection with Section 12.3(b), then the Recipient Party shall (i) [***]; (ii) [***]; (iii) [***]; and (iv) [***], *provided* always that nothing in this Section 12.3 shall require the Recipient Party to breach or otherwise violate any applicable court order, Applicable Law, or the listing rules of any exchange on which such Party's securities (or the securities of its parent entity) are traded.

12.4 [***]. Nothing in this Agreement shall prevent a Party from [***]. A Party shall [***].

12.5 **Disclosure of Agreement.** Notwithstanding the foregoing, either Party may disclose the relevant terms of this Agreement to the extent required, in the reasonable opinion of such Party's counsel, to comply with the listing rules of any exchange on which such Party's securities (or the securities of its parent entity) are traded, *provided* that such Party shall: (a) [***]; (b) [***]; (c) [***]; and (d) [***], *provided* that [***].

12.6 **Ongoing Obligation for Confidentiality.** Following the expiration or early termination of this Agreement, each Party and its Affiliates shall [***], upon request of the Disclosing Party, return to the other Party or destroy, at [***] election, any Confidential Information of the other Party or any of its Affiliates, *provided* that the other Party may retain one (1) copy of such Confidential Information for the sole purpose of performing any continuing obligations under this Agreement, as required by Applicable Law, or for legal archival purposes, and, *provided further* that upon expiry of the [***] Royalty Term with respect to a given [***] Licensed Product, such [***] Licensed Product and all related [***] Licensed IP shall not be returned or destroyed. Notwithstanding the foregoing, such other Party also may retain such additional copies of or any computer records or files containing such Confidential Information that have been created solely by such Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such other Party's standard archiving and back-up procedures, but not for any other use or purpose. All such copies of Confidential Information retained or archived as permitted under this Agreement remain subject to the obligations of confidentiality and non-use set out in this Agreement.

12.7 **Use of Name.** Except as expressly permitted in this Agreement, (including in connection with any authorized disclosure under Section 12.3, Section 12.5, Section 12.8 or Section 12.9) neither Party shall use the name, logo, or trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance, [***]. The restrictions imposed by this Section 12.7 shall not prohibit either Party from making any disclosure identifying the other Party that, in the reasonable opinion of the disclosing Party's counsel, is required by Applicable Law.

12.8 **Publicity.** Except as expressly permitted under Section 12.3, Section 12.5, Section 12.7, this Section 12.8, or Section 12.9, neither Party shall make any public announcement regarding this Agreement without the prior written consent of the other Party ([***]), except for those disclosures reiterating information for which consent has already been obtained for the relevant purpose, *provided* that [***].

12.9 **Press Release.** Promptly following the Effective Date, the Parties shall issue a mutually agreed joint press release announcing the execution of this Agreement.

12.10 **Publication.**

(a) If BioNTech proposes to make any scientific or other publication or presentation that [***], BioNTech shall provide Autolus with an advance copy of each proposed publication or presentation at least [***] prior to its proposed date of publication or presentation. Autolus will have [***] to review and provide any comments on the proposed publication or presentation and BioNTech shall [***]. BioNTech shall comply with any written request of Autolus (i) to delete Autolus's Confidential Information from such publication or presentation and (ii) withhold publication or presentation for an additional [***] in order to permit Autolus to obtain Patent protection in accordance with the terms of this Agreement. BioNTech shall acknowledge Autolus's contribution and authorship according to customary standards.

(b) Save as permitted under the relevant Technologies License Agreement, BioNTech shall not have the right to make any scientific or other publication or presentation regarding any information BioNTech may generate during the performance of the Evaluation, *provided* that [***].

(c) Autolus may make any scientific or other publication or presentation; *provided* that, such publications or presentations shall not contain any Confidential Information of BioNTech and if Autolus proposes to make any scientific or other publication or presentation that (i) [***], or (ii) [***], Autolus shall provide BioNTech with an advance copy of each proposed publication or presentation at

least [***] prior to its proposed date of publication or presentation. BioNTech will have [***] to review and provide any comments on the proposed publication or presentation and Autolus shall [***]. Autolus shall comply with any written request of BioNTech (1) to delete BioNTech's Confidential Information from such publication or presentation and (2) withhold publication or presentation for an additional [***] in order to permit BioNTech to obtain Patent protection in accordance with the terms of this Agreement. Autolus shall acknowledge BioNTech's contribution and authorship according to customary standards.

13. Term and Termination

13.1 Term; Effect of Expiration.

(a) Notwithstanding any provision to the contrary set forth in this Agreement, (i) this Section 13.1(a), Section 14.3 (Survival), Article 17 (Governing Law and Dispute Resolution), Article 18 (General Provisions), and Article 1 (solely with respect to defined terms used in the foregoing Sections or Articles) will be effective as of the Execution Date, and (ii) all other terms of this Agreement will be automatically effective as of the Effective Date. If the Initial Closing has not occurred within [***] following the Execution Date, [***].

(b) The term of this Agreement will commence upon the Effective Date and expire: (i) with respect to the [***] License, on a [***] Licensed Product-by-[***] Licensed Product and country-by-country basis until the expiration of the last to expire [***] Royalty Term with respect to such [***] Licensed Product in such country, and finally in its entirety with respect to all [***] Licensed Products in all countries upon expiration of the [***] Royalty Term with respect to the last [***] Licensed Product in the last country in the Territory; (ii) with respect to the Obe-Cel Revenue Interest, upon the expiration of the Obe-cel Revenue Interest Term; and (iii) in its entirety upon the later of clause (i) and (ii) above, in each case, unless earlier terminated as permitted by this Agreement (the "Term").

(c) Following the expiration of the [***] Royalty Term with respect to a given [***] Licensed Product and country, the license grant in Section 5.1 for such [***] Licensed Product and country shall automatically become fully paid-up, perpetual, irrevocable and royalty-free.

13.2 Termination for Material Breach; Insolvency.

(a) If either Autolus or BioNTech is in material breach of any material obligation hereunder, then the non-breaching Party may give written notice to the breaching Party specifying the claimed particulars of such material breach, and if such material breach is not cured within [***] after the breaching Party's receipt of such notice, or, if such breach (other than with respect to undisputed payments under this Agreement) is not capable of being cured within [***] after the breaching Party's receipt of such notice, the non-breaching Party may terminate this Agreement immediately by giving written notice to the breaching Party to such effect *provided* that if the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party, and such alleged breaching Party provides the other Party notice of such dispute within [***], then the other Party shall not have the right to terminate this Agreement under this Section 13.2(a) unless and until the dispute resolution process in accordance with Section 17.2, has determined that the alleged breaching Party has materially breached a material obligation under the Agreement and such Party has failed to cure such breach within [***] following such decision.

(b) Autolus may terminate this Agreement on [***] written notice if BioNTech fails to pay Autolus the Upfront Payment when due and such failure to pay is not cured within such [***] period.

(c) Either Autolus or BioNTech may terminate this Agreement on written notice if an Insolvency Event occurs in relation to the other Party.

13.3 **Termination by BioNTech Without Cause**. BioNTech may terminate this Agreement on a [***] Licensed Product-by-[***] Licensed Product basis or in its entirety (a) on [***] prior written notice to Autolus if the First Commercial Sale of a [***] Product has not occurred or (b) on [***] prior written notice to Autolus if the First Commercial Sale of a [***] Product has occurred.

14. Effects of Termination.

14.1 **Upon Termination.** Upon termination, but not expiry, of this Agreement:

(a) All licenses granted to BioNTech in respect of the [***] Licensed IP under Section 5.1 terminate; *provided* that upon termination of this Agreement for any reason, upon the request of any Sublicensee of BioNTech who is not then in breach of its sublicense agreement or the terms and conditions of this Agreement applicable to such Sublicensee, Autolus will enter into a direct license to such Sublicensee on the same terms as the relevant terms of this Agreement, taking into account any difference in license scope, territory and duration of sublicense grant;

(b) To the extent not prohibited by Applicable Law, BioNTech shall wind down any ongoing Clinical Trials with respect to any [***] Licensed Product in a manner and on a timeline reasonably determined by BioNTech and, in each case, consistent with BioNTech's ethical obligations;

(c) If applicable, BioNTech and its Affiliates and Sublicensees shall be entitled, during the [***] period following such termination, to sell any commercial inventory of such [***] Licensed Product which remains on hand as of the date of the termination, including any further Commercialization activities in connection with the same, and to continue the Manufacture of in-progress [***] Licensed Product, so long as BioNTech pays to Autolus the royalties applicable to such subsequent sales in accordance with the terms and conditions set forth in this Agreement;

(d) Each Receiving Party shall return or destroy all Confidential Information of the Disclosing Party to the extent requested pursuant to Section 12.6; and

(e) Solely if such termination was by Autolus pursuant to Section 13.2(b), the Obe-cel Revenue Interest payments set out in Section 7.5 shall terminate as of the effective date of termination.

14.2 **BioNTech's Options.** Upon termination of this Agreement, to the extent that any MCSA Negotiation Period, Product Option Period, or Technologies Option Period have not expired, such periods shall expire with effect from the effective date of termination.

14.3 **Survival.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the provisions of [***].

15. Warranties and Covenants

15.1 **Warranties by Each Party.** Each Party warrants to the other Party, as of the Effective Date that:

(a) it is an entity duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;

(b) it has full corporate power and authority to execute, deliver, and perform this Agreement, and has taken all corporate action required by law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

(c) this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms;

(d) all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained other than any such consents, approvals and authorizations that may be required under Antitrust Laws, including the HSR Act, with respect to any Technologies Option, other option exercise or any other

collaboration contemplated by this Agreement (including the MCSA and the Research and Development Collaboration Agreement); and

(e) the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby do not: (i) conflict with or result in a breach of any provision of its organizational documents; (ii) result in a breach of any other agreement to which it is a party; or (iii) violate any Applicable Law.

15.2 Warranties by Autolus

Except as disclosed in Schedule 15.2, Autolus warrants to BioNTech, as of the Effective Date that:

(a) Except for those rights licensed to Autolus under the Upstream License Agreements, Autolus is the sole and exclusive owner of all of the Autolus IP and the Autolus IP is free from encumbrances;

(b) Autolus has the right to grant to BioNTech the rights that Autolus purports to grant BioNTech hereunder, including the right to grant: the Product Options; exclusive licenses under the [***] Licensed IP, [***] Licensed IP and [***] Licensed IP; co-exclusive and non-exclusive licenses under the Activity Enhancement Licensed IP; non-exclusive licenses under the Safety Switch Licensed IP and non-exclusive internal research license under the Technologies Option IP to conduct the Evaluation, in each case subject to, and as further set out in, the terms of this Agreement;

(c) Autolus has, prior to the Effective Date, obtained and provided BioNTech with true, accurate and complete copies of, all relevant consents and waivers from Third Parties, including [***] that enable Autolus to grant, as of the Effective Date (with regards to the [***] License and Obe-cel Revenue Interest and the non-exclusive internal research license under the Technologies Option IP to conduct the Evaluation) or anytime immediately after the Effective Date (with regards to each of the options within the Product Option and Technologies Option), the rights to BioNTech that are contemplated under this Agreement without any further action required to be taken;

(d) to Autolus's Knowledge, the Development, Manufacture and Commercialization of the [***], the Obe-cel Products, the Autolus Products, and the Option Products does not violate any license and does not infringe or misappropriate any intellectual property rights of any Third Party;

(e) Autolus and its Affiliates have conducted, and to Autolus's Knowledge, their respective consultants and subcontractors have conducted, all research, Development, Manufacture, and other Exploitation of the [***], the Obe-cel Products, the Autolus Products, and the Option Products in material compliance with all Applicable Law;

(f) other than the Upstream License Agreements, there are no agreements or other arrangements to which Autolus or any of its Affiliates is a party relating to the Autolus IP that materially restrict (i) BioNTech's ability to research, Develop, Manufacture, use, import, offer for sale, sell, have sold and otherwise Commercialize [***] Licensed Products or (ii) Autolus's ability to research, Develop, Manufacture, use, import, offer for sale, sell, have sold and otherwise Commercialize the Autolus Products, the Obe-Cel Products or the Option Products;

(g) neither Autolus nor any of its Affiliates are delinquent in any payment obligations to any Third Party, or engaged in any dispute with any Third Party, in each case, that, to Autolus's Knowledge, would limit (i) BioNTech's ability to research, Develop, Manufacture, use, import, offer for sale, sell, have sold and otherwise Commercialize [***] Licensed Products or (ii) Autolus's ability to research, Develop, Manufacture, use, import, offer for sale, sell, have sold and otherwise Commercialize the Obe-cel Product, the Autolus Products, or the Option Products;

(h) no claims, challenges, oppositions, nullity actions, interferences, inter-partes reexaminations, inter-partes reviews, post-grant reviews, derivation proceedings or other proceedings are pending or, to Autolus's Knowledge, have been threatened: (i) as to the Autolus Patents, including any seeking to invalidate or otherwise challenge the Autolus Patents; or (ii) asserting that Autolus is

infringing or has misappropriated or otherwise is violating any Patent right, trade secret, or other proprietary right of any Third Party as would reasonably be expected to impair the ability of Autolus to fulfil any of its obligations or BioNTech to exercise any of its rights under this Agreement;

(i) to Autolus's Knowledge, no Third Party is infringing, misappropriating, or otherwise violating, or threatening to infringe, misappropriate or otherwise violate, the Autolus IP;

(j) the inventions claimed, covered or encompassed by the Autolus IP (i) were not conceived, discovered, developed, invented, or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States (or any agency thereof) or the government of any other country, (ii) are not a "subject invention" as that term is described in 35 U.S.C. § 201(e), (iii) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, codified at 35 U.S.C. §§ 200-212, or any regulations promulgated pursuant thereto, including in 37 C.F.R. Part 401, (iv) in the case of clauses (ii) or (iii), are not subject to similar obligations or restrictions under the Applicable Law of any other country, and (v) are not the subject of any licenses, options or other rights of any Governmental Authority, within or outside the United States;

(k) Schedule 15.2(k) contains all Autolus Patents that are Controlled by Autolus as of the Effective Date;

(l) all issued Autolus Patents are subsisting, and to Autolus's Knowledge, are not invalid or unenforceable, in whole or in part;

(m) to Autolus's Knowledge, (i) the Autolus Patents are being diligently prosecuted in the respective patent offices in the Territory in accordance with Applicable Law, (ii) Autolus has not taken any action that would render any invention claimed in the Autolus Patents unpatentable, and (iii) the Autolus Patents have been filed and maintained properly and correctly, and all necessary ownership and priority right assignments from named inventors to Autolus have been procured and timely filed and recorded with appropriate patent offices;

(n) all required application, registration, maintenance, other related fees and renewal fees in respect of the Autolus Patents have been paid and all necessary documents and certificates have been filed with the relevant agencies for the purpose of obtaining or maintaining the Autolus Patents;

(o) all current and former officers, employees, agents, advisors, consultants, contractors or other representatives of Autolus or any of its Affiliates who are inventors of or have otherwise contributed in a material manner to the creation or development of any Autolus IP have, where Applicable Law does not automatically vest such individual's rights in Autolus, executed and delivered to Autolus or any such Affiliate a valid and enforceable written assignment or other agreement regarding the protection of proprietary information and the assignment to Autolus of any Autolus IP;

(p) to Autolus's Knowledge, no Person who claims to be an inventor of an invention claimed in an Autolus Patent is not identified as an inventor of such invention in the filed patent documents for such Autolus Patent;

(q) to Autolus's Knowledge, no dispute regarding inventorship, authorship, or ownership has been alleged or threatened with respect to any Autolus IP;

(r) Autolus and its Affiliates have taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality and value of all Autolus Know-How that constitutes trade secrets under Applicable Law, including by requiring all employees, consultants and subcontractors to execute binding and enforceable agreements requiring all such employees, consultants and subcontractors to maintain the confidentiality of all such Know-How;

(s) there are no claims, judgements, settlements, litigations, suits, actions, disputes, arbitration, judicial or legal, administrative or other proceedings, or governmental investigations pending or, to Autolus's Knowledge, threatened against Autolus or any of its Affiliates that could reasonably be expected to adversely affect or restrict the ability of Autolus to consummate or perform the transactions

and obligations contemplated under this Agreement, or that would affect the Autolus IP, Autolus's Control thereof, or the [***] Licensed Products, the Autolus Products, the Obe-Cel Products, or the Option Products;

(t) Autolus is not in material breach of or material default under the Upstream License Agreements and has not taken or failed to take any action that with or without notice, lapse of time or both would constitute a material breach of or material default under the Upstream License Agreements;

(u) the Upstream License Agreements, to Autolus's Knowledge, are valid, binding, enforceable, and in full force and effect, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity);

(v) Autolus has received no written notice regarding any material violation, breach, or default under the any Upstream License Agreements;

(w) Autolus has not waived any rights under any Upstream License Agreements in a manner that would adversely affect in any material respect BioNTech's rights hereunder;

(x) the Upstream License Agreements are the only agreements under which Autolus receives rights under the Autolus IP, and Autolus has provided BioNTech with true, complete, and correct copies of each such Upstream License Agreement; and

(y) [***] has, as required by [***], consented to [***] under this Agreement.

15.3 **Warranties by BioNTech**. BioNTech warrants to Autolus, as of the Effective Date that neither it, nor its Affiliates, develops, sells or manufactures tobacco products or makes the majority of its profits from the importation, marketing, sale or disposal of tobacco products.

15.4 **Covenants.**

(a) Each Party hereby covenants that it shall not employ or use the services of any Person who is debarred under the United States Federal Food, Drug and Cosmetic Act or comparable laws in any other country or jurisdiction, in connection with the Exploitation of [***] Licensed Products (in the case of BioNTech) or the Exploitation of Obe-cel Products and Option Products (in the case of Autolus). If a Party becomes aware of the debarment or threatened debarment of any Person providing services to such Party (including the Party itself and its Affiliates, and any Autolus Licensees and Sublicensees (as applicable)) that directly or indirectly relate to activities under this Agreement, such Party shall [***] notify the other Party in writing.

(b) Autolus hereby covenants it shall not (1) [***], and (2) [***], unless [***]:

(i) breach its obligations under any Upstream License Agreement in any way that results in, or would reasonably be expected to result in, the termination of such Upstream License Agreement;

(ii) modify or amend any Upstream License Agreement in any way that would adversely affect BioNTech's rights hereunder in any material respect, without BioNTech's prior written consent, [***]. Following any modification or amendment to an Upstream License Agreement, Autolus shall provide BioNTech with a copy of the applicable modification to or amendment of the applicable Upstream License Agreement, [***];

(iii) terminate any Upstream License Agreement in whole or in part without BioNTech's prior written consent, [***]; and

(iv) within [***] after Autolus's knowledge thereof, provide BioNTech with notice of and information relating to any alleged or suspected breach or default by Autolus or the other party(s) to the Upstream License Agreements that would adversely affect in any material respect Autolus or BioNTech or its rights hereunder and, following BioNTech's request, reasonably consult with BioNTech before taking any action in relation to such alleged or suspected breach or default.

(c) Each Party hereby covenants that it shall not, and shall not permit its Affiliates, Autolus Licensees (in the case of Autolus) or Sublicensees (in the case of BioNTech) or anyone acting on its or their behalf under this Agreement to grant or otherwise convey to any Third Party any rights that would be inconsistent with the other Party's rights hereunder.

(d) Neither Autolus nor its Affiliates shall grant any option, right or license to any Third Party under the Autolus IP in a manner that conflicts with any of the rights or licenses granted to BioNTech, or any obligations of Autolus, hereunder.

(e) If Autolus receives notice of an alleged payment default by Autolus or its Affiliates under any Upstream License Agreement that Autolus does not cure within [***], Autolus hereby grants to BioNTech the right (but not the obligation) to: (i) [***]; and (ii) [***]. The foregoing shall not preclude any other right or action that BioNTech may have against Autolus for such breach of Section 15.4(b)(iv).

(f) If Autolus has not obtained and provided to BioNTech prior to the Effective Date: (i) [***]; and (ii) [***], in each case ((i) and (ii)), then Autolus will [***]. In each case, [***].

15.5 No Other Warranties. Except as expressly stated in this Article 15: (a) no representation, condition or warranty whatsoever is made or given by or on behalf of BioNTech or Autolus; and (b) all other conditions and warranties, whether arising by operation of law or otherwise, are hereby expressly excluded, including any conditions and warranties of merchantability, fitness for a particular purpose or non-infringement.

15.6 Upstream Obligations. Notwithstanding anything to the contrary in this Agreement, the licenses and rights granted hereunder are subject to those terms of the Upstream License Agreements that are set out in Schedule 15.6, and BioNTech will, and will procure that its Affiliates, Subcontractors and Sublicensees will, comply with such terms set forth in Schedule 15.6 to the extent applicable. Subject to the foregoing, and without limitation to any remedy that may be available to Autolus, if [***], then [***].

15.7 Compliance.

(a) **Compliance with Anti-Corruption Laws.** In connection with this Agreement, the Parties shall comply with all applicable local, national, and international laws, regulations, and industry codes dealing with government procurement, conflicts of interest, corruption or bribery, including, if applicable, the U.S. Foreign Corrupt Practices Act of 1977, as amended ("FCPA"), the UK Bribery Act 2010, as amended, any laws enacted to implement the Organisation of Economic Cooperation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions, and any other applicable equivalent laws. Without limiting the foregoing, in performing its obligations under this Agreement, neither Party shall, directly or indirectly, pay any money to, or offer or give anything of value to, any Government Official, in order to obtain or retain business or to secure any commercial or financial advantage for any Party, including the other Party or for itself or any of their respective Affiliates or Autolus Licensees or Sublicensees (as applicable).

(b) **Prohibited Conduct.** Without limiting the other obligations of the Parties set forth in this Section 15.7, each Party covenants to the other that, as of the Effective Date and in the performance of its obligations under this Agreement through the expiration or termination of this Agreement, such Party and, to its knowledge, its Affiliates and its and its Affiliates' employees and contractors, in connection with the performance of their respective obligations under this Agreement, have not made, offered, given, promised to give, or authorized, and shall not make, offer, give, promise to give, or authorize, any bribe, kickback, payment or transfer of anything of value, directly or indirectly through Third Parties, to any Government Official for the purpose of (i) improperly influencing any act or

decision of the Government Official, (ii) inducing the Government Official to do or omit to do an act in violation of a lawful or otherwise required duty, (iii) securing any improper advantage, or (iv) inducing the Government Official to improperly influence the act or decision of any organization, including any government or government instrumentality, to assist any Party in obtaining or retaining business. If, during the Term of this Agreement, either Party becomes aware that any Person acting on that Party's behalf has engaged in any prohibited conduct pursuant to this Section 15.7(b) related to the performance of such Party's obligations under this Agreement, then such Party will [***]; *provided* that, [***].

(c) **Compliance with Export Control and Sanctions Laws.** In connection with this Agreement, (i) the Parties shall comply with all applicable local, national, and international laws, and regulations regarding export controls, economic sanctions, trade embargoes, and anti-boycott matters including sanctions regulations administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC"), and the Office of Financial Sanctions Implementation in the United Kingdom, and (ii) except as permitted by applicable government license or authorization, each Party shall not engage in any direct or indirect transactions or dealings with (including export, reexport, or transfer of any items to) (1) any country or territory that is subject to an embargo by the U.S. government, European Union or the United Kingdom, or (2) any Person identified on, or fifty percent (50%) or more owned (individually or in the aggregate) by Persons identified on, any list of designated or prohibited parties maintained by the United States, the European Union or the United Kingdom or other applicable jurisdictions (including the List of Specially Designated Nationals and Blocked Persons, the Foreign Sanctions Evaders List, and the Sectoral Sanctions Identifications List, which are maintained by OFAC, and the Entity List, Denied Persons List, and Unverified List, which are maintained by the Bureau of Industry and Security of the U.S. Commerce Department).

(d) **Compliance with Data Protection Laws.** In connection with this Agreement the Parties are independent Data Controllers (as defined in the EU GDPR and UK GDPR) in respect of the Personal Data provided by Autolus to BioNTech (the "**Shared Personal Data**") and shall disclose, make available, transfer, store, use and process the Shared Personal Data in accordance with Applicable Data Protection Law. Without limiting the obligations of the Parties set forth in Applicable Data Protection Law, each Party covenants to the other that it shall: (i) provide such assistance to the other Party as is reasonably required to enable the other Party to comply with requests by patients to exercise their rights under, and within the time limits imposed by, Applicable Data Protection Law; (ii) have in place throughout the term of this Agreement appropriate technical and organizational security measures to prevent the unauthorized or unlawful processing of the Shared Personal Data and the accidental loss or destruction of, or damage to, the Shared Personal Data, and to ensure a level of security appropriate to the harm that might result from such unauthorized or unlawful processing or accidental loss, destruction or damage and the nature of the Shared Personal Data to be protected; (iii) ensure that any transfer of the Shared Personal Data other than to the United Kingdom or within the European Economic Area is either to a country approved under the EU GDPR or UK GDPR as providing adequate protection, or that there are appropriate safeguards or binding corporate rules in place pursuant to the EU GDPR or UK GDPR, or one of the derogations for specific situations in the EU GDPR or UK GDPR applies to the transfer; and (iv) inform the other Party of any Personal Data Breach (as defined in the EU GDPR and UK GDPR) irrespective of whether there is a requirement to notify any applicable data protection authority or patients.

15.8 **Compliance with Applicable Laws.** (a) Autolus and BioNTech shall coordinate and cooperate fully with each other in mutually determining whether any filings or submissions pursuant to Antitrust Laws or Foreign Investment Laws in connection with the transactions contemplated hereby would be necessary, (b) if BioNTech determines that any such filings or submissions, including HSR Filings, are required with respect to BioNTech's exercise of any Technologies Option, other option exercise, or any other collaboration contemplated by this Agreement (including but not limited to the MCSA and Research and Development Collaboration Agreement), then the Parties shall cooperate to make an HSR Filing within [***] (unless otherwise agreed to in writing by counsel for the Parties), and any other filings or submissions under other Antitrust Laws or Foreign Investment Laws [***], and (c) any information required to be provided under this Agreement by one Party to the other or to the JSC shall be subject to applicable Antitrust Laws relating to the exchange of competitively sensitive information. The Parties shall cooperate with one another to the extent necessary in the preparation of any such filings or submissions, shall consult and cooperate with each other in connection with obtaining HSR Clearance (if required) and all other required clearances under other Antitrust

Laws or Foreign Investment Laws and shall [***] resolve [***] any objections that may be asserted by any applicable Governmental Authority with respect to the transactions notified in any such filings or submissions, including HSR Filings. Each Party shall be responsible for its own costs and expenses associated with any such filings. [***] shall be responsible for the filing fees associated with any such filings or submissions under Antitrust Laws or Foreign Investment Laws, including any HSR Filing. Notwithstanding any other terms of this Agreement, (i) if BioNTech, after coordinating and consulting with Autolus, determines that an HSR Filing is required with respect to BioNTech's exercise of any Technologies Option, including the [***] Option or the [***] Option, no option exercise fee shall be payable until after the date of HSR Clearance with respect to the applicable disclosure and (ii) any such option exercise will not be effective prior to receipt of any approvals, non-disapprovals, or expirations or terminations of any applicable waiting period in jurisdictions (if any) where necessary filings or submissions pursuant to Antitrust Laws or Foreign Investment Laws are to be made.

15.9 Regulatory Efforts.

(a) **Cooperation for Antitrust/Foreign Investment approvals.** Without limiting the foregoing, neither Autolus nor BioNTech, and none of their Affiliates, without the consent of the other Party, shall enter into any agreement with any Governmental Authority pursuant to which Autolus, BioNTech or any of their respective Affiliates, as applicable, agree not to consummate the transactions contemplated hereunder, withdraw any filing, or authorize the extension of any investigation, for any period of time. Each Party shall (i) notify the other [***] upon the receipt by it or any Affiliates of any communication from any Governmental Authority in connection with the transactions contemplated by this Agreement, (ii) permit the other to review in advance any proposed communication by either Party to any Governmental Authority, (iii) provide copies of all communications received from or provided to any Governmental Authority in connection with the transactions contemplated by this Agreement; and (iv) provide advance notice of any meeting, whether in person or by telephone or video conference, with any Governmental Authority in connection with the transactions contemplated by this Agreement and, [***], allow the other to attend unless prohibited by such Governmental Authority. Each Party shall, and shall cause their Affiliates to, [***] collaborate in reviewing and commenting on in advance, provide information and providing such assistance as the other may reasonably request in connection with, and to consult the other on, any (proposed) filing, notification or submission made with, or (proposed) communication with, any Governmental Authority in connection with any filing, submission, investigation or inquiry in connection with the transactions contemplated by this Agreement; *provided, however*, that (1) a party may designate any competitively sensitive materials provided to the other as "outside counsel only," and such materials and information shall be given only to outside counsel of the recipient and will not be disclosed by such outside counsel to employees, officers, or directors of the recipient without the advance written consent of the party providing such materials, and (2) a party may redact such materials to comply with contractual arrangements, and address reasonable attorney-client or other established legal privilege concerns, to the extent they are not governed by a common interest privilege or doctrine.

(b) **Other Conduct Prior to Antitrust/Foreign Investment approvals.** Notwithstanding anything to the contrary in this Agreement, this Section 15.9 and [***] does not require that either Party: (i) offer, negotiate, commit to, or effect, by consent decree, hold separate order, trust or otherwise, the sale, divestiture, license or other disposition of any capital stock, assets, rights, products or businesses of it or any of its Affiliates; (ii) agree to any restrictions on its or its affiliates' business(es); or (iii) pay any amount or take any other action to prevent, effect the dissolution of, vacate, or lift any decree, order, judgment, injunction, temporary restraining order or other order in any suit or proceeding that would otherwise have the effect of preventing or delaying the transactions contemplated by this Agreement (collectively, an "**Antitrust Remedy**" or "**Foreign Investment Remedy**"), where such Antitrust Remedy or Foreign Investment Remedy would have a material effect on its ability to operate, exercise control or otherwise enjoy any part of its business(es), including any part of its business transferred or contemplated to be transferred by the transactions contemplated in this Agreement.

(c) **Outside Date for Any Antitrust/Foreign Investment Approvals .** If any filings or submissions, including HSR Filings, are required under Antitrust Laws or Foreign Investment Laws with respect to BioNTech's exercise of any Technologies Option, other option exercise, or any other collaboration contemplated by this Agreement (including but not limited to the MCSA and Research and Development Collaboration Agreement), for each such option or collaboration, the option exercise shall

be deemed withdrawn or the collaboration abandoned if such option or collaboration has not become effective on the date that is [***] following the applicable option exercise date or execution of an agreement contemplated hereunder for failure to obtain the necessary approvals, non-disapprovals, or expirations or terminations of any applicable waiting period in jurisdictions where necessary filings or submissions pursuant to Antitrust Laws or Foreign Investment Laws are to be made (the “**Option End Date**”), unless agreed otherwise by the parties; *provided, however*, the rights under this Section 15.9(c) shall not be available to any Party whose breach of this Agreement has been a principal cause of or resulted in the failure of the effectiveness of the option or collaboration to occur on or before the Option End Date.

16. Indemnification; Liability

16.1 **Indemnification by Autolus.** Autolus shall indemnify BioNTech, its Affiliates, and their respective officers, directors, and employees (the “**BioNTech Indemnitees**”) from and against any and all liabilities, damages, losses, costs, fees, or expenses of any nature (including reasonable attorneys’ fees and litigation expenses) (“**Losses**”) incurred by or imposed upon the BioNTech Indemnitees or any of them in connection with any Claim to the extent arising or resulting from: (a) Autolus’s or any of its Affiliates’, (sub)licensees’ or contractors’ Exploitation of Obe-cel Product (including, for clarity, actual or alleged infringement of any Third Party’s intellectual property); (b) the gross negligence or willful misconduct of Autolus or any Autolus Indemnitee; and (c) the material breach of any provision (including any representation or warranty) of this Agreement by Autolus; *provided*, that Autolus shall not be obliged to so indemnify the BioNTech Indemnitees for any Claims to the extent that BioNTech has an indemnification obligation to an Autolus Indemnitee under Section 16.2.

16.2 **Indemnification by BioNTech.** BioNTech shall indemnify Autolus, its Affiliates, their respective officers, directors, and employees (the “**Autolus Indemnitees**”) from and against any and all Losses incurred by or imposed upon the Autolus Indemnitees or any of them in connection with any Claim, in each case, to the extent arising or resulting from: (a) BioNTech’s, or any of its Affiliates’, Sublicensees’ or Subcontractors’ Development of a [***] Licensed Binder or a [***] Licensed Binder or Exploitation of [***] Licensed Products; (b) the gross negligence or willful misconduct of BioNTech or any BioNTech Indemnitee; or (c) the material breach of any provision of this Agreement by BioNTech; *provided*, that BioNTech shall not be obliged to so indemnify the Autolus Indemnitees for any Claims to the extent that Autolus has an indemnification obligation to a BioNTech Indemnitee under Section 16.1.

16.3 Indemnification Procedure; Settlement; Quantification.

(a) If any of the BioNTech Indemnitees or Autolus Indemnitees (the “**Indemnified Parties**”) receives written notice of the commencement of any Claim, and such Indemnified Party intends to seek indemnification pursuant to this Article 16, then the Indemnified Party shall [***] provide BioNTech (if such Indemnified Party is a BioNTech Indemnitee) or Autolus (if such Indemnified Party is a Autolus Indemnitee) written notice of such Claim, and such Party shall provide the other Party (the “**Indemnifying Party**”) with written notice of such Claim within [***] of its receipt of notice from the Indemnified Party, stating the nature, basis and the amount thereof, to the extent known, along with copies of the relevant documents evidencing such Claim and the basis for indemnification sought. Failure of the Indemnified Party to give such notice within the time frame specified will not relieve the Indemnifying Party from its indemnification obligations hereunder, except to the extent that the Indemnifying Party is actually and materially prejudiced thereby.

(b) The Indemnifying Party may assume the defense, appeal or settlement proceedings of the Indemnified Party against the Claim with counsel of its choice. The Indemnified Party may retain separate co-counsel at its sole cost and expense and participate in the defense, appeal or settlement proceedings of the Claim, and cooperate, and cause the individual indemnitees to cooperate, with the Indemnifying Party in the defense, settlement or compromise of such Claim.

(c) In no event shall the Indemnifying Party compromise or settle any claim or suit in a manner which admits fault or negligence on the part of the Indemnified Parties without the prior written consent of the Indemnified Party. The Indemnified Party and the Indemnifying Party will act in

good faith in responding to, defending against, settling or otherwise dealing with Claims. The Indemnified Party and the Indemnifying Party will also cooperate in any such defense, appeal or settlement proceedings, and give each other reasonable access to all information relevant thereto. Whether or not the Indemnifying Party has assumed the defense, appeal or settlement proceedings with respect to a Claim, such Indemnifying Party will not be obligated to indemnify the Indemnified Party for any settlement entered into or any judgment that was consented to without the Indemnifying Party's prior written consent ([***]).

16.4 **Insurance.** Each Party shall maintain, at its own cost, insurance with respect to its activities and obligations under this Agreement in such amounts as are commercially reasonable in the industry for companies conducting similar business and shall require any of its Affiliates undertaking activities under this Agreement to do the same. BioNTech may fulfill the foregoing insurance obligations through self-insurance.

16.5 **Special, Indirect and other Losses.** Except for [***], neither Party nor any of its Affiliates shall be liable in contract, tort, negligence breach of statutory duty or otherwise for any special, indirect, incidental, punitive or consequential damages or for any economic loss or loss of profits suffered by the other Party, regardless of any notice of the possibility of such damages.

16.6 **After-Tax Basis.** All payments made under Section 16.1 and Section 16.2 shall be on an after-tax basis. "After-tax basis" shall mean that the amount payable pursuant to the indemnities given by the Parties under Section 16.1 and Section 16.2 will be calculated in such a manner as will ensure that, after taking into account: (a) the amount of any Tax payable by the Indemnified Party as a result of the payment being subject to Tax in the hands of the Indemnified Party (or would be subject to Tax but for a relief (save for any relief described in (b))); and (b) all reliefs that arise to the Indemnified Party in respect of either that Tax or a matter giving rise to the payment, the Indemnified Party is in the same position as it would have been in if the matter giving rise to the payment had not occurred.

17. Governing Law and Dispute Resolution

17.1 **Governing Law.** This Agreement is governed by, and will be interpreted in accordance with, the substantive laws of [***] without giving effect to any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The provisions of the United Nations Convention on Contracts for the International Sale of Goods are expressly excluded.

17.2 **Dispute Resolution.** In the event of any disputes, controversies or differences between the Parties, arising out of, in relation to, or in connection with this Agreement, including any alleged breach of this Agreement or any issue relating to the formation, scope, validity, construction, interpretation, enforceability, breach, performance, application, or termination of this Agreement a ("**Dispute**"), then upon the written request of either Party, the Parties agree to a meeting of the appropriate subject matter expert at each Party, and discuss in good faith an amicable resolution thereof. If the Dispute is not resolved within [***] following the written request for amicable resolution, then either Party may then escalate the matter to the [***]. If [***] cannot resolve the Dispute within [***] following escalation thereto for amicable resolution, and a Party wishes to pursue the matter, it may commence litigation. The Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the courts in [***] for the resolution of all Disputes.

17.3 **Patent Disputes.** As between the Parties, notwithstanding anything herein to the contrary, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent shall [***]. With respect to any Patent issues related to the enforceability or validity of a Patent, [***].

17.4 **Specific Performance.** The Parties agree that irreparable damage may occur if [***] this Agreement was not performed in accordance with the terms thereof and that each Party may seek specific performance of the terms thereof, in addition to any other remedy to which it is entitled at law or in equity. It is therefore agreed that each Party may seek a temporary, preliminary, or permanent injunction or injunctions to prevent breaches of [***] this Agreement, without posting any bond or other undertaking, in addition to any other remedy to which they are entitled at law or in equity, and if any action should be brought in equity to enforce any of the provisions of [***] this Agreement, the other Party shall not raise the defense that there is an adequate remedy at law.

18. General Provisions

18.1 Assignment.

(a) Neither Party may assign or transfer this Agreement or its rights and obligations under this Agreement without [***], except that, and without prejudice to Section 18.1(b) (a) [***] this Agreement or its rights and obligations under this Agreement [***] without [***]; and (b) [***] this Agreement [***] without [***]; *provided* that [***] this Agreement [***] and this Agreement [***]. The assigning Party shall provide the other Party with [***] written notice of any such assignment. Any permitted assignee shall assume all obligations of its assignor under this Agreement ([***]). Any attempted assignment in contravention of the foregoing is void. This Agreement is binding upon and inures to the benefit of the Parties hereto and their respective successors and permitted assigns.

(b) Autolus may:

(i) enter into an Obe-cel Product Transaction at any time, *provided* that [***] in accordance with the terms of the foregoing Section 18.1(a), Autolus shall [***] pursuant to which [***];

(ii) subject to [***], enter into an Option Product or Next Gen Option Product Transaction at any time, *provided* that, [***] in accordance with the terms of the foregoing Section 18.1(a), Autolus shall [***] pursuant to which [***];

(iii) enter into a [***] Transaction at any time, *provided* that, [***] in accordance with the terms of the foregoing Section 18.1(a), Autolus shall [***]; and

(iv) enter into a Technologies Option Transaction at any time, *provided* that, [***] in accordance with the terms of the foregoing Section 18.1(a) [***], Autolus shall [***].

For clarity, [***].

18.2 **Force Majeure.** No Party shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to a cause beyond the reasonable control of a Party, including acts of God, fires, floods, earthquakes, acts of war, terrorism, or civil unrest, or hurricane or other inclement weather, explosions, embargoes, epidemics, pandemics, quarantines, or any other event similar to those enumerated above (“**Force Majeure**”); *provided*, that the affected Party [***] notifies the other Party, and *provided further* that the affected Party shall [***] avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with the utmost dispatch whenever such causes are removed. Such excuse from liability will be effective only to the extent and duration of the Force Majeure event causing the failure or delay in performance and *provided* that a Party has not caused such events to occur. When such circumstances arise, the Parties shall [***].

18.3 **Extension to Affiliates.** Without prejudice to the provisions of any Section in this Agreement that explicitly refers to a Party’s Affiliates, the Parties agree that any Affiliates of a Party may exercise any of the rights granted to such Party in this Agreement or perform any of such Party’s obligations in this Agreement *provided* that such Party shall be responsible for the performance of any of its obligations that are performed by its Affiliates.

18.4 **Severability.** Should one (1) or more of the provisions of this Agreement become invalid or unenforceable as a matter of law, then this Agreement shall be construed as if such provision were not contained herein and the remainder of this Agreement shall be in full force and effect, and the Parties will [***] substitute for the invalid or unenforceable provision a valid and enforceable provision that conforms as nearly as possible with the original intent of the Parties.

18.5 **Waivers and Amendments.** The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be

effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

18.6 **Relationship of the Parties.** It is expressly agreed that the Parties shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall have the authority to make any statements, representations or commitments of any kind or to take any action that will be binding on the other Party without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party. The Parties (and any successor, assignee, transferee, or Affiliate of a Party) shall not treat or report the relationship between the Parties arising under this Agreement as a partnership for tax purposes, unless required by Applicable Law.

18.7 **Notices.** All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when: (a) delivered by hand (with written confirmation of receipt); (b) when received by the addressee, if sent by an internationally recognized overnight delivery service (receipt requested), or (c) delivered by electronic mail followed by delivery via either of the methods set forth in Section 18.7(a) or Section 18.7(b), in each case, to the appropriate addresses set forth below (or to such other addresses as a Party may designate by notice):

If to Autolus:

Autolus Limited and Autolus Holdings (UK) Limited
The Mediaworks
191 Wood Lane
London
England
W12 7FP
Attn: General Counsel
Email: [***]

with a copy to:

Cooley LLP
11951 Freedom Drive
One Freedom Square
Reston Town Center
Reston, VA 20190-5656
Attn: [***]
Telephone: [***]
Email: [***]

If to BioNTech:

BioNTech SE
An d. Goldgrube 12,
55131 Mainz,
Germany
Attn: [***]
Email: [***]

with a copy to:

[***]
Attn: [***]
Email: [***]

18.8 **Further Assurances.** BioNTech and Autolus each hereby covenant and agree, without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary to carry out the intent and purposes of this Agreement.

18.9 **Compliance with Law.** Each Party shall perform its obligations under this Agreement in accordance with all Applicable Laws. No Party shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any Applicable Law.

18.10 **No Third Party Beneficiary Rights.** Except for the rights of Sublicensees under Section 14.1(a), the provisions of this Agreement are for the sole benefit of the Parties and no other Person or entity shall have any right or claim against either Party by reason of these provisions or be entitled to enforce any of these provisions against either Party (including under the Contracts (Rights of Third Parties) Act 1999). The rights of the Parties to amend this Agreement are not subject to the consent of any other Person.

18.11 **English Language.** This Agreement is written and executed in the English language. Any translation into any other language shall not be an official version of this Agreement and, in the event of any conflict in interpretation between the English version and such translation, the English version shall prevail. All notices and other communications given under this Agreement shall be in the English language.

18.12 **Interpretation.** In this Agreement, unless otherwise specified: (a) “includes” and “including” shall mean respectively includes and including without limitation; (b) “hereof,” “herein,” and “herewith,” and words of similar import, shall, unless otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement; (c) “in writing” or “written” includes any mode of reproducing words in a legible and non-transitory form, including emails and faxes, unless another form is prescribed by Applicable Law; (d) “or” is disjunctive but not necessarily exclusive; (e) a Party includes its permitted assignees or the respective successors in title to substantially the whole of its undertaking; (f) a statute or statutory instrument or any of their provisions is to be construed as a reference to that statute or statutory instrument or such provision as the same may have been or may from time to time hereafter be amended or re-enacted in accordance with any requirements with respect to such amendment or re-enactment; (g) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders; (h) the Exhibits, Schedules and other attachments form part of the operative provision of this Agreement and references to this Agreement shall, unless the context otherwise requires, include references to the Exhibits, Schedules and attachments; (i) the headings in this Agreement are for information only and shall not be considered in the interpretation of this Agreement; (j) general words shall not be given a restrictive interpretation by reason of their being preceded or followed by words indicating a particular class of acts, matters or things; (k) the word “any” shall mean “any and all” and (l) “shall” has the same meaning as “will” wherever referenced, and vice versa. The Parties agree that the terms and conditions of this Agreement are the result of negotiations between the Parties and that this Agreement shall not be construed in favor of or against any Party by reason of the extent to which any Party participated in the preparation of this Agreement.

18.13 **Expenses.** Except as otherwise expressly provided in this Agreement, each Party shall pay the fees and expenses of its respective lawyers and other experts and all other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution and delivery of this Agreement.

18.14 **Entire Agreement.** This Agreement, together with its Schedules, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter, including, for clarity, the confidentiality agreement entered into by [***] dated [***]. Each Party acknowledges that in entering into this Agreement it does not rely on, and shall have no remedies in respect of, any statement, representation, assurance or warranty (whether made innocently or negligently) that is not set out in this Agreement. Each Party agrees that it shall not have any claim for innocent or negligent misrepresentation based on any statement in this Agreement. In the event of any inconsistency between the terms of this Agreement and the pharmacovigilance agreement entered into pursuant to Section 5.12(b) the terms of this Agreement shall prevail and govern, except to the extent such conflicting terms relate directly to the pharmacovigilance responsibilities of the Parties (including the exchange of safety data), in which case the terms of the pharmacovigilance agreement shall prevail and govern.

18.15 **Counterparts.** This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile or electronically transmitted signatures (including .pdf) and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

18.16 **Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

[***]

In Witness Whereof, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives as of the Execution Date.

BIONTECH SE

By: /s/ Ryan Richardson

Name: Ryan Richardson

Title: Management Board Member and Chief Strategy Officer

By: /s/ Sierk Poetting

Name: Sierk Poetting

Title: Management Board Member and Chief Operating Officer

AUTOLUS LIMITED

By: /s/ Christian Itin

Name: Christian Itin

Title: Chief Executive Officer

AUTOLUS HOLDINGS (UK) LIMITED

By: /s/ Christian Itin

Name: Christian Itin

Title: Chief Executive Officer

SIGNATURE PAGE TO LICENSE AGREEMENT

SCHEDULE 1.8
ACTIVITY ENHANCEMENT LICENSED TECHNOLOGY

[**]

SCHEDULE 1.27
AUTO1/22 PRODUCT

[**]

SCHEDULE 1.29
AUTO6NG PRODUCT

[**]

SCHEDULE 1.30

[*] PRODUCT**

[***]

SCHEDULE 1.36
BASEBALL ARBITRATION

[**]

SCHEDULE 1.38
[] LICENSED BINDER**

[**]

SCHEDULE 1.60
[] LICENSED BINDERS**

[**]

SCHEDULE 1.61
[] LICENSED BINDERS**

[**]

SCHEDULE 1.152
OBE-CEL PRODUCT

SCHEDULE 1.191
SAFETY SWITCH

[**]

SCHEDULE 1.227
[] LICENSED BINDER**

[**]

SCHEDULE 1.228
[] LICENSED BINDER**

[**]

SCHEDULE 3.1
MANUFACTURING AND COMMERCIAL SERVICES AGREEMENT TERMS

[***]

SCHEDULE 3.1(B)
PROCESS TIMELINES

SCHEDULE 4.4(A)
PRODUCT AGREEMENT TERMS

[***]

SCHEDULE 6.2
TRANSFERRED MATERIALS

SCHEDULE 6.5
FORM TECHNOLOGIES LICENSE AGREEMENT

SCHEDULE 15.2
AUTOLUS DISCLOSURES

[**]

SCHEDULE 15.2(K)
AUTOLUS PATENTS

[**]

SCHEDULE 15.6
UPSTREAM OBLIGATIONS

[**]

Subsidiary	Jurisdiction of Incorporation
BioNTech (Shanghai) Pharmaceuticals Co., Ltd	China
BioNTech Australia Pty Ltd	Australia
BioNTech BioNTainer Holding GmbH	Germany
BioNTech Cell & Gene Therapies GmbH	Germany
BioNTech Delivery Technologies (US), LLC	Delaware
BioNTech Delivery Technologies GmbH	Germany
BioNTech Diagnostics GmbH	Germany
BioNTech Europe GmbH	Germany
BioNTech Idar-Oberstein Services GmbH	Germany
BioNTech Individualized mRNA Manufacturing GmbH	Germany
BioNTech Innovation and Services Marburg GmbH	Germany
BioNTech Innovation GmbH	Germany
BioNTech Innovative Manufacturing Services GmbH	Germany
BioNTech Israel Ltd.	Israel
BioNTech Manufacturing GmbH	Germany
BioNTech Manufacturing Marburg GmbH	Germany
BioNTech Pharmaceuticals Asia Pacific Pte. Ltd.	Singapore
BioNTech Pharmaceuticals Spain S.L.U.	Spain
BioNTech R&D (Austria) GmbH	Austria
BioNTech Real Estate Holding GmbH	Germany
BioNTech Real Estate Verwaltungs GmbH	Germany
BioNTech Research and Development, Inc.	Delaware
BioNTech Rwanda Ltd.	Rwanda
BioNTech Sénégal Suarl	Senegal
BioNTech Switzerland GmbH	Switzerland
BioNTech Taiwan Co. Ltd.	Taiwan
BioNTech Turkey Tıbbi Ürünler Ve Klinik Araştırma Ticaret Anonim Şirketi	Turkey
BioNTech UK Limited	UK
BioNTech US Inc.	Delaware
BioNTech USA Holding LLC	Delaware
InstaDeep DE GmbH	Germany
InstaDeep LLC	Delaware
InstaDeep Ltd	UK
InstaDeep Nigeria Limited	Nigeria

Subsidiary	Jurisdiction of Incorporation
InstaDeep SARL	Tunisia
InstaDeep SAS	France
JPT Peptide Technologies GmbH	Germany
JPT Peptide Technologies, Inc.	Delaware
New Technologies Re	Luxembourg
NT Security and Services GmbH	Germany
reSano GmbH	Germany

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Ugur Sahin, certify that:

1. I have reviewed this annual report on Form 20-F of BioNTech SE;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 20, 2024

By:

/s/ Prof. Dr. Ugur Sahin

Prof. Dr. Ugur Sahin

Chief Executive Officer

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jens Holstein, certify that:

1. I have reviewed this annual report on Form 20-F of BioNTech SE;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 20, 2024

By: _____ /s/ Jens Holstein

Jens Holstein
Chief Financial Officer

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

The certification set forth below is being submitted in connection with the Annual Report on Form 20-F for the year ended 2023 (the "Report") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

I, Ugur Sahin, Chief Executive Officer of BioNTech SE (the "Company"), certify that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 20, 2024

By: _____
/s/ Prof. Dr. Ugur Sahin
Prof. Dr. Ugur Sahin
Chief Executive Officer

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

The certification set forth below is being submitted in connection with the Annual Report on Form 20-F for the year ended 2023 (the "Report") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

I, Jens Holstein, Chief Financial Officer of BioNTech SE (the "Company"), certify that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 20, 2024

By: _____
/s/ Jens Holstein
Jens Holstein
Chief Financial Officer

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-8 No. 333-253263) pertaining to the 2020 Employee Equity Plan, the 2020 Restricted Stock Unit Plan for North America Employees, the 2017 Employee Stock Ownership Plan and the 2020 Management Board ESOP of BioNTech SE,
- (2) Registration Statement (Form S-8 No. 333-269740) pertaining to the 2020 Employee Equity Plan, 2020 Restricted Stock Unit Plan for North America Employees and 2021 Employee Stock Ownership Plan of BioNTech SE, and
- (3) Registration Statement (Form S-8 No. 333-277105) pertaining to the 2024 Non-North America Employee Participation Plan and 2024 North America Employee Participation Plan of BioNTech SE,

of our reports dated March 20, 2024, with respect to the consolidated financial statements of BioNTech SE and the effectiveness of internal control over financial reporting of BioNTech SE included in this Annual Report (Form 20-F) of BioNTech SE for the year ended December 31, 2023.

/s/ EY GmbH & Co. KG Wirtschaftsprüfungsgesellschaft

Cologne, Germany

March 20, 2024

BioNTech SE
Compensation Clawback Policy
Adopted November 29, 2023

Purpose

The Supervisory Board (the “**Board**”) of BioNTech SE (the “**Corporation**”) has adopted this compensation clawback policy (the “**Policy**”) which provides for the recoupment of incentive-based compensation in the event of an accounting restatement. This Policy is intended to comply with Section 10D of the Securities Exchange Act of 1934 (the “**Act**”) and the rules promulgated thereunder by the U.S. Securities and Exchange Commission (“**SEC**”), any other applicable rules and regulations of the SEC, the listing standards of Nasdaq, and the laws of the jurisdiction in which the Corporation is organized or has its principal place of business (collectively, the “**Applicable Rules**”), and will be interpreted consistent therewith.

Applicability and Effective Date

This Policy is effective October 2, 2023 (the “**Effective Date**”) and is applicable to all Incentive-Based Compensation (as defined below) received by Executive Officers (as defined below) after the Effective Date. The Policy will be administered by the Board or, if so designated by the Board, the Compensation, Nominating and Corporate Governance Committee of the Board (the “**Committee**”), in which case references to the Board will be deemed to be references to the Committee. Any determination made by the Board under this Policy will be final and binding on all affected individuals. Each Executive Officer shall be required to execute the acknowledgement in Appendix A of this Policy as soon as practicable after the later of (i) the Effective Date and (ii) the date on which the employee is designated as an Executive Officer; provided, however, that failure to execute such acknowledgement shall have no impact on the enforceability of this Policy.

Restatement Clawback

In the event the Corporation is required to prepare an Accounting Restatement (as defined below), any Executive Officer who received Excess Compensation (as defined below) during the three (3) completed fiscal years preceding the date the Corporation is required to prepare an Accounting Restatement (the “**Look-Back Period**”) shall be required to repay or forfeit such Excess Compensation reasonably promptly. For purposes of this Policy, the date the Corporation is required to prepare an Accounting Restatement is deemed to be the earlier of the date (i) the Board (or a designated committee thereof) concludes, or reasonably should have concluded, that the Corporation is required to prepare an Accounting Restatement, or (ii) a court, regulator, or other legally authorized body directs the Corporation to prepare an Accounting Restatement.

Method of Repayment; Conditions for Non-Recovery

The Board shall have discretion to determine the appropriate means of recovery of Excess Compensation, which may include, without limitation, direct payment in a lump sum from the Executive Officer, recovery over time, cancellation of outstanding awards, the reduction of future pay and/or awards, and/or any other method which the Board determines is advisable to achieve reasonably prompt recovery of Excess Compensation. At the direction of the Board, the Corporation shall take all actions reasonable and appropriate to recover Excess Compensation from any applicable Executive Officer, and such Executive Officer shall be required to reimburse the Corporation for any and all expenses reasonably incurred (including legal fees) by the Corporation in recovering such Excess Compensation in accordance with this Policy.

The Committee, or in the absence of the Committee, a majority of the independent directors on the Board, may determine that repayment of Excess Compensation (or a portion thereof) is not required only where it determines that recovery would be impracticable and one of the following circumstances exists: (i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered, provided the Corporation has (A) made a reasonable attempt to recover such Excess Compensation, (B) documented such reasonable attempt, and (C) provided such documentation to Nasdaq; (ii) recovery would violate home country law where the law was adopted

prior to November 28, 2022, provided the Corporation has (A) obtained an opinion of home country counsel acceptable to Nasdaq that recovery would result in such violation and (B) provided such opinion to the Nasdaq; or (iii) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Corporation, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and the regulations thereunder.

No Fault Application, No Indemnification

Recovery of Excess Compensation under this Policy is on a “no fault” basis, meaning that it will occur regardless of whether the Executive Officer engaged in misconduct or was otherwise directly or indirectly responsible, in whole or in part, for the Accounting Restatement. No Executive Officer may be indemnified by the Corporation, or any of its affiliates, from losses arising from the application of this Policy.

Definitions

For purposes of this Policy, the following definitions will apply:

“Accounting Restatement” means an accounting restatement due to the material noncompliance of the Corporation with any financial reporting requirement under securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that corrects an error that is not material to previously issued financial statements but would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

Changes to financial statements that do not constitute an Accounting Restatement include retroactive: (i) application of a change from one generally accepted accounting principle to another generally accepted accounting principle; (ii) revisions to reportable segment information due to a change in internal organization; (iii) reclassification due to a discontinued operation; (iv) application of a change in reporting entity, such as from a reorganization of entities under common control; (v) adjustments to provisional amounts in connection with a prior business combination; and (vi) revisions for stock splits, reverse stock splits, stock dividends, or other changes in capital structure.

“Excess Compensation” means any amount of Incentive-Based Compensation received by an Executive Officer after commencement of service as an Executive Officer that exceeds the amount of Incentive-Based Compensation that otherwise would have been received had it been determined based on the Accounting Restatement, computed without regard to any taxes and social security paid. For Incentive Compensation based on stock or American Depositary Share (“ADS”) price or total shareholder return, where the amount to be recovered is not subject to mathematical recalculation directly from information in the Accounting Restatement, the amount to be recovered shall be based on a reasonable estimate of the effect of the Accounting Restatement on the stock or ADS price or total shareholder return, as applicable, and the Corporation shall retain documentation of the determination of such estimate and provide such documentation to Nasdaq if so required by the Applicable Rules. Incentive-Based Compensation is deemed received during the fiscal year during which the applicable financial reporting measure, stock or ADS price and/or total shareholder return measure, upon which the payment is based, is achieved, even if the grant or payment occurs after the end of such period.

“Executive Officer” means an individual who is, or was during the Look-Back Period, an executive officer of the Corporation within the meaning of Rule 10D-1(d) under the Act. A determination that an individual is an Executive Officer for the purposes of this Policy shall not imply that she or he is an “executive officer” of the Corporation with respect to any other requirement of applicable law.

“Incentive-Based Compensation” means any compensation that is granted, earned or vested based wholly or in part on stock or ADS price, total shareholder return, and/or the attainment of (i) any financial reporting measure(s) that are determined and presented in accordance with the accounting principles used in

preparing the Corporation's financial statements and/or (ii) any other measures that are derived in whole or in part from such measures.

Compensation that does not constitute "Incentive-Based Compensation" includes equity incentive awards for which the grant is not contingent upon achieving any financial reporting measure performance goal for an individual to receive such award and that vest exclusively upon completion of a specified employment period, without any performance condition, and bonus awards that are discretionary or based on subjective goals or goals unrelated to financial reporting measures.

Administration, Amendment, and Termination

This Policy will be enforced and, if applicable, appropriate proxy disclosures and exhibit filings will be made in accordance with the Applicable Rules. The terms of this policy shall be construed and/or enforced in accordance with the Applicable Rules.

The Board shall have authority to (i) exercise all of the powers granted to it under the Policy, (ii) construe, interpret, and implement this Policy, and (iii) make all determinations necessary or advisable in administering this Policy.

In addition, the Board may amend this Policy from time to time in its discretion, and shall amend this Policy as it deems necessary, including to reflect changes in applicable law. The Board may terminate this Policy at any time in accordance with the Applicable Rules. Any such amendment (or provision thereof) or termination shall not be effective if such amendment or termination would (after taking into account any actions taken by the Corporation contemporaneously with such amendment or termination) cause the Corporation to violate the Applicable Rules.

The terms contained in this Policy are intended to be construed in addition to any terms contained in any Executive Officer employment or service agreement. In the event of any conflict or inconsistency between this Policy and any other policies, plans, or other materials of the Corporation (including any agreement between the Corporation and any Executive Officer subject to this Policy), this Policy will govern.

This Policy will be deemed to be automatically updated to incorporate any requirement of law, the SEC, exchange listing standard, rule or regulation applicable to the Corporation.

Appendix A:
BioNTech SE
Compensation Clawback Policy

ACKNOWLEDGMENT

The undersigned acknowledges and agrees that the undersigned (i) is, and will be, subject to the Compensation Clawback Policy (the "Policy") to which this acknowledgement is appended with respect to any Incentive-Based Compensation received on or after October 2, 2023, and (ii) will abide by the terms of the Policy, including by returning Excess Compensation (as defined in the Compensation Clawback Policy) pursuant to whatever method the Board determines is advisable to achieve reasonably prompt recovery of such Excess Compensation, as prescribed under the Policy.

Capitalized terms used but not defined have the meanings set forth in the Policy.

Print Name

Signature

Dated:

