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

FORM 20-F

☐ 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, 2022

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)

An der Goldgrube 12
D-55131 Mainz
Germany
(Address of principal executive offices)

Prof. Ugur Sahin, M.D.,
c/o BioNTech SE
An der Goldgrube 12
D-55131 Mainz
Germany
+49 6131-9084-0 (Tel), +49 6131 9084-390 (Fax), info@biontech.de (E-mail)
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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*

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 20, 2023, the most recent practicable date, no par value: 240,993,998

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 has filed 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).
<table>
<thead>
<tr>
<th>TABLE OF CONTENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>GENERAL INFORMATION</td>
</tr>
<tr>
<td>CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS</td>
</tr>
<tr>
<td>PART I</td>
</tr>
<tr>
<td>ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS</td>
</tr>
<tr>
<td>ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE</td>
</tr>
<tr>
<td>ITEM 3. KEY INFORMATION</td>
</tr>
<tr>
<td>A. [Reserved]</td>
</tr>
<tr>
<td>B. Capitalization and Indebtedness</td>
</tr>
<tr>
<td>C. Reasons for the Offer and Use of Proceeds</td>
</tr>
<tr>
<td>D. Risk Factors</td>
</tr>
<tr>
<td>ITEM 4. INFORMATION ON THE COMPANY</td>
</tr>
<tr>
<td>A. History and Development of the Company</td>
</tr>
<tr>
<td>B. Business Overview</td>
</tr>
<tr>
<td>C. Organizational Structure</td>
</tr>
<tr>
<td>D. Property, Plant and Equipment</td>
</tr>
<tr>
<td>ITEM 4A. UNRESOLVED STAFF COMMENTS</td>
</tr>
<tr>
<td>ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS</td>
</tr>
<tr>
<td>A. Operating Results</td>
</tr>
<tr>
<td>B. Liquidity and Capital Resources</td>
</tr>
<tr>
<td>C. Research and Development, Patents and Licenses, etc.</td>
</tr>
<tr>
<td>D. Trend Information</td>
</tr>
<tr>
<td>E. Critical Accounting Estimates</td>
</tr>
<tr>
<td>ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES</td>
</tr>
<tr>
<td>A. Directors and Senior Management</td>
</tr>
<tr>
<td>B. Compensation</td>
</tr>
<tr>
<td>C. Board Practices</td>
</tr>
<tr>
<td>D. Employees</td>
</tr>
<tr>
<td>E. Share Ownership</td>
</tr>
<tr>
<td>ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS</td>
</tr>
<tr>
<td>A. Major Shareholders</td>
</tr>
<tr>
<td>B. Related Party Transactions</td>
</tr>
<tr>
<td>C. Interests of Experts and Counsel</td>
</tr>
<tr>
<td>ITEM 8. FINANCIAL INFORMATION</td>
</tr>
<tr>
<td>A. Consolidated Statements and Other Financial Information</td>
</tr>
<tr>
<td>B. Significant Changes</td>
</tr>
<tr>
<td>ITEM 9. THE OFFER AND LISTING</td>
</tr>
<tr>
<td>A. Offer and Listing Details</td>
</tr>
<tr>
<td>B. Plan Of Distribution</td>
</tr>
<tr>
<td>C. Markets</td>
</tr>
</tbody>
</table>
## Table of Contents

D. Selling Shareholders 193  
E. Dilution 193  
F. Expenses of the Issue 194  

**ITEM 10. ADDITIONAL INFORMATION**  
A. Share Capital 194  
B. Memorandum and Articles of Association 194  
C. Material Contracts 199  
D. Exchange Controls 199  
E. Taxation 200  
F. Dividends and Paying Agents 209  
G. Statement by Experts 209  
H. Documents on Display 209  
I. Subsidiary Information 210  

**ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK** 210  

**ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES** 211  
A. Debt Securities 211  
B. Warrants and Rights 211  
C. Other Securities 211  
D. American Depositary Shares 212  

**PART II**  

**ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES** 213  
**ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS** 213  
**ITEM 15. CONTROLS AND PROCEDURES** 213  
**ITEM 16. [RESERVED]** 214  
**ITEM 16A. Audit Committee Financial Expert** 214  
**ITEM 16B. Code of Ethics** 214  
**ITEM 16C. Principal Accountant Fees and Services** 214  
**ITEM 16D. Exceptions from the Listing Standards for Audit Committees** 215  
**ITEM 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers** 215  
**ITEM 16F. Changes in Registrant’s Certifying Accountant** 216  
**ITEM 16G. Corporate Governance** 216  
**ITEM 16H. Mine Safety Disclosure** 227  
**ITEM 16I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections** 227  

**PART III**  

**ITEM 17. FINANCIAL STATEMENTS** 227  
**ITEM 18. FINANCIAL STATEMENTS** 227  
**ITEM 19. EXHIBITS** 228
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, RibosCytokine, RibofMab, Recon, Neo-Stim, Precision Neo-Stim, and Maptac, 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.

3
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:

- our expected revenues and net profits 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;
- 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;
- 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 the COVID-19 pandemic 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 of the following 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.

Investing in the ADSs involves various risks. You should carefully read and consider the matters discussed in this Annual Report under the heading “Risk Factors,” which include the following risks:

Risk Factor Summary

• Demand for our COVID-19 vaccine, though difficult to predict, is expected 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.

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

• We have only recently built our marketing and sales organization. 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.
• 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.
• 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.
• 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 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 related 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 expect 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 beyond the current pandemic, including when 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 coverage 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-offs 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 fiscal 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.

For example, for the year ended December 31, 2022, Pfizer 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 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 are likely to change as we receive final data from Pfizer for the year ended December 31, 2022 in accordance with the reporting cycle of its 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.
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.

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 re-design 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. In addition, 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 foreign regulatory authorities. If problems are identified during the review or inspection of these manufacturers or
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.

Our COVID-19 vaccine was 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 preclinical 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.

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 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, even if coverage is limited. 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 the European Union.

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

10
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. For example, the U.S. government released a “blueprint,” which is a plan to reduce the cost of drugs. The blueprint contains certain measures that the HHS is already working to implement. At 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.

The imposing of export controls on our COVID-19 vaccine in the European Union or in other jurisdictions could severely and adversely impact our manufacturing activities, commercial activities and financial results.

Governments of the jurisdictions in which we or our partners produce our COVID-19 vaccine may prohibit us from delivering orders of our COVID-19 vaccine to customers in other jurisdictions.

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. The European Union ended this export authorization scheme as of December 31, 2021, however, if they reenact this scheme, we may be prohibited from exporting commercial supplies of the vaccine from our manufacturing site in Germany to non-EU countries (and Pfizer may likewise be prohibited from exporting out of its manufacturing site in Belgium). Such restrictions may have a material impact on our manufacturing or distribution activities, and the commercialization of our COVID-19 vaccine.

Our ability to continue to generate income from sales of our COVID-19 vaccine is uncertain, due to government interest and public perception regarding a vaccine, as well as the evolving nature of the disease more generally.

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.

In addition, there is a heightened risk that a COVID-19 vaccine may be subject to adverse emergency actions taken by governmental entities in certain countries, including intellectual property expropriation, compulsory licenses, strict price controls or other actions. In the U.S., the Defense Production Act of 1950, as amended (the “Defense Production Act”), gives the U.S. government rights and authorities that may directly or indirectly diminish our own rights or economic opportunities with respect to our COVID-19 vaccine. Our current and potential third-party service providers may be impacted by government entities potentially invoking the Defense Production Act or other potential restrictions to all or a portion of services they might otherwise offer. The Biden administration has previously invoked, and may continue using, the Defense Production Act to expand manufacturing capacity of vaccine and vaccine supplies as well as COVID-19 tests and testing supplies.

Additionally, we may need to, or we may be required by governmental or non-governmental authorities to, set aside specific quantities of doses of our COVID-19 vaccine for designated purposes or geographic areas. We face challenges related to the allocation of supply of our COVID-19 vaccine, particularly with respect to geographic distribution.
Furthermore, public sentiment regarding commercialization of a COVID-19 vaccine, the safety and efficacy of our COVID-19 vaccine, other COVID-19 vaccines and treatments, the COVID-19 pandemic generally, as well as public perception of the severity of SARS-CoV-2 virus may limit or negate our ability to generate income from sales of our COVID-19 vaccine. We believe that social media is increasingly being used to communicate and misrepresent information about the COVID-19 pandemic and our and other COVID-19 vaccines. If social media posts and other communications contain negative, inaccurate or misleading information about our COVID-19 vaccine, demand for our COVID-19 vaccine may be diminished and we may suffer 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, University of Oxford/AstraZeneca plc, China National Pharmaceutical Group (Sinopharm)/Beijing Institute of Biological Products and Wuhan Institute of Biological Products, Novavax, Inc., Valneva SE/Dynavax Technologies Corporation, Sinovac Biotech Ltd., and Bharat Biotech International Limited, and other companies are in late stages of clinical development or have been authorized for emergency use or approved in certain countries. 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 successfully commercialize 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 U.S. for individuals 6-months to 12 years of age and approval for use in certain other countries. Our COVID-19 vaccine has not yet been approved by regulatory authorities in many of such countries. We and Pfizer intend to continue to observe our COVID-19 vaccine and vaccines 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, 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.

We are developing other product candidates 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 face intense competition from drugs that have already been approved and accepted by the medical community for the treatment of the conditions for which we may develop drugs in the future. We also expect to face competition from new drugs that enter the market. There are a number of drugs 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 all 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.

Our competitors may develop or commercialize products 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 or biotechnology companies, providing them with an advantage over us. Our competitors therefore may be more successful in commercializing their products than we are, which could adversely affect our competitive position and business. Competitive products may make any products we develop obsolete or non-competitive before we can recover the expenses of developing and commercializing our products, if approved.

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 never achieve or maintain profitability 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 never achieve or maintain profitability 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 product sales revenue.

We have only recently developed our sales, distribution or marketing capabilities in Germany and Turkey, 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. To further successfully commercialize our COVID-19 vaccine and any other products that may result from our development programs, 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 a significant internal team or 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 maintain profitability depends in part on our 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 maintain profitability 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 and pandemics, such as the COVID-19 pandemic, 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 genetic research 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. 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, if any of our products are approved for marketing, we or a collaborator will be 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 provided a new Medicare Part D coverage gap discount program. Considerable uncertainty remains regarding the implementation and impact of the ACA.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. The Tax Cuts and Jobs Act of 2017, or the TCJA, includes a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” CMS proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on October 13, 2017, an executive order was signed terminating the cost-sharing reduction, or CSR, subsidies that reimburse insurers under the ACA. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. Another executive order was signed directing federal agencies with authorities and responsibilities under the ACA to waive, defray, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, penalty or regulatory burden on individuals, health insurers, health providers, or manufacturers of pharmaceuticals or medical devices. With the current presidential administration and Congress, there may be additional administrative or legislative changes, including modification, repeal or replacement of all, or certain provisions of, the ACA. However, it remains to be seen whether new legislation modifying the ACA will be enacted and, if so, precisely what the new legislation will provide, when it will be enacted and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. The implications of a potential repeal or replacement of the ACA, for our and our collaborators’ business and financial condition, if any, are not yet clear.

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.

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

We intend to seek approval to market our product candidates in both the United States and in other selected jurisdictions. If we obtain approval for our 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 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

Profitability is difficult to maintain over time and highly dependent on various factors.

Our ability to continue to generate revenue and maintain 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 sales transactions, 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 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;
• 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 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 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;
• our ability 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 our share repurchase plan;
• 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 off 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;

19
• 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 COVID-19 pandemic or its impact 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 reports or results 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 commercialization of our COVID-19 vaccines, 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 American Depositary Shares, or ADSs) in connection with our public offerings, generation of proceeds under our collaboration agreements, secured bank loans and issuance of a convertible note. As of December 2022, our original COVID-19 vaccine product has been authorized or approved for emergency or temporary use or granted marketing authorization in more than 100 countries and regions worldwide and our efforts have resulted in more than 4 billion doses shipped globally. 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. 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 expansion of sites in Germany and new sites in the United States, and potentially others 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 non-tax group entities, though we have not recognized deferred tax assets related to such loss carryforwards for International Financial Reporting Standards, or IFRS, reporting purposes until December 31, 2022. 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 in tax liabilities. As described above, we incurred significant net losses in every year since our inception other than 2018, 2021 and 2022 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 German 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. As a result of an internal review, we discovered that especially in the most recent years, where a significant volume of service providers have been engaged to ensure research, development, manufacturing and general supply capabilities of our COVID-19 vaccine, and certain of our subsidiaries did not withhold, report and remit certain wage taxes and social security contributions in connection with the contract service providers where some have been engaged in a manner comparable to internal employees as required to be withheld under German tax and social security laws, and have not made the requisite recordings in our and their financial books and records in relation to such wage taxes and social security contributions. We notified the tax authorities of these possible late payments. No administrative offense or criminal proceeding have been opened as of the date of this report.

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 paid 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 such 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 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, and we cannot be certain that additional funding will be available on favorable terms, or at all. We are currently generating product sales or royalty revenue to finance our operations. However, should this change 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 changing nature of the COVID-19 pandemic 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 capital 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, 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 will need to continue to develop and expand our company, and we may encounter difficulties in managing this 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 assertion 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 we may not be able to effectively implement our internal control over financial reporting. Any failure to achieve and maintain an effective system of internal control over financial reporting and disclosure controls and procedures may result in loss of investor confidence in the reliability of our financial statements, which could harm our business.

The Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, contains significant corporate governance and executive compensation related provisions that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. 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 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.

As a result of an internal review, we discovered that especially in the most recent years, where a significant increase of shipments took place, international trade obligations such as correct customs value calculation of our and certain of our subsidiaries have not been applied correctly and we have made the requisite recordings in our financial books and records in relation to such customs duties. We notified the customs authorities of these possible late payments. No administrative offense or criminal proceeding have been opened as of the date of this report. The expenses are partially subject to reimbursement under our collaboration agreement with Pfizer.

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 fiscal 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 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.

In accordance with our Nasdaq listing, 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 ADRs less attractive as a result, and there may be a less active trading market for the ADRs.

We face risks related to catastrophic global events including natural disasters, political crises, or public health epidemics and pandemics, such as the COVID-19 pandemic, 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 tensions related to Russia’s actions in Ukraine, 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.
Inflation and rapid uncertainty and liquidity concerns in the broader financial services industry remain.

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 and clinical trials. We are dedicating resources to exploring additional avenues for more adequate coverage as our business evolves. With the grant of marketing approvals for our COVID-19 vaccine we have acquired additional insurance coverage for losses relating to transportation and storage of our COVID-19 vaccine and product liability claims arising from its use. 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.

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 used to support operations in the U.S., 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 deposits 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.
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 its 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 COVID-19 vaccine and Moderna’s mRNA-1273, no mRNA immunotherapies have been approved or received emergency use authorization or conditional marketing authorization to date by the FDA, the EMA or other comparable regulatory authority. 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-based medicines do not irreversibly change cell DNA. 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. Additionally, the COVID-19 pandemic continues to have an impact on our ability to monitor trial safety related to, for
example, staff shortages due to contracting COVID-19 or the global shortage in healthcare professionals, re-assignment of
staff to treat COVID-19 patients and restricted clinical site access. 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 those 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, the COVID-19 pandemic 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; 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. Furthermore, the FDA or other regulatory authorities may disagree with our clinical trial design or 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. The COVID-19 pandemic has introduced additional challenges in enrolling patients into many of our clinical trials. 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 of the COVID-19 global pandemic; 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. As discussed above, each of the foregoing risks is exacerbated by the COVID-19 pandemic currently affecting the global community and the global economy.

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;
• 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 pandemic continues to impact our operations, including our clinical trial operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, 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.

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 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.
Some 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 will 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 flexibility over 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, failure to succeed in preclinical studies or clinical trials or 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, provide accurate information to the FDA, the EMA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or 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 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, provide accurate information to the FDA, the EMA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or 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.

Employee litigation and unfavorable publicity could negatively affect our future business.

From time to time our employees may bring lawsuits 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 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 COVID-19 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. In addition, thefts of inventory at warehouses, plants or 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 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 to 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. 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, we and a vendor have separately in the past been subject to a security breach resulting in us unknowingly making payments to third parties that were able to gain unauthorized access to our and the vendor’s email systems. Additionally, 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 product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any 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;

39
We carry clinical trial insurance, including product liability insurance, which we believe to be sufficient in light of our current commercial operations and clinical programs; however, we cannot be certain that our insurance will not be sufficient or that we will not be able to maintain such coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We have expanded our insurance coverage to include product liability claims arising from the use of our COVID-19 vaccine; however, the amount of coverage we have obtained may not be adequate, and we may be unable to maintain product liability insurance for our COVID-19 vaccine on commercially reasonable terms in the future. 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 ADS 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 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 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.

Our ability to effectively monitor and respond to the rapid and ongoing developments and expectations relating to environmental, social and governance (“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 market value of our common 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 supply chain, and human resource development, which may result in increased regulatory, social or other scrutiny on us. Regarding climate risks, we are expected to 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 (“dual materiality”). With regard to human rights risks, we are addressing increasingly complex regulatory requirements, including German legislation (for example, the Act on Corporate Due Diligence Obligations for the Prevention of Human Rights Violations in Supply Chains (“Lieferkettensorgfaltspflichtengesetz - LKSG”)) and legislative planning by the European Union. 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. 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 market value of our common 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, share price, 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 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 (e.g. the United States) different from our manufacturing sites (e.g. Germany). 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 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 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 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 our product candidates for clinical trials or our products for patients, if approved, 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, due to the custom nature of the equipment and single-use assemblies, we may not be able to supply this expanded need reliably without significant investments. 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 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.

As certain of our product candidates are manufactured for each individual patient, we will be required to maintain a chain of identity with respect to each patient’s tissue sample, sequence data derived from such tissue sample, analyze results of such patient’s genomic analysis and the custom manufactured product for each 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 and the construction of a novel modular manufacturing facilities in Africa and Australia that we refer to as “BioNTainers”. 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 recently introduced BioNTainers, 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 also face the risk of inventory write-offs 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.

43
under our agreements with CMOs due to planned new formulations, adaptations of our COVID-19 vaccine and increased internal manufacturing capacities. Significant inventory write-offs or redundant manufacturing expenses would negatively impact our results of operations.

Our facilities are subject to various regulatory requirements and may be subject to the inspection of the FDA or other regulatory authorities.

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 facilities inadequate for the manufacture of our COVID-19 vaccine or our product candidates or 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 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 or as a result of labor disputes or, in the case of jurisdictions into which we intend to expand our operations, unstable political environments. If we were to encounter any of these difficulties, our ability to provide our COVID-19 vaccine or our product candidates to patients in clinical trials, or to provide products for the treatment of patients, once approved, 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 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 may 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 establish additional manufacturing capabilities and expand to other locations or geographies, 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 the required personnel, and generally manage our growth effectively, the development and production of our 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 the suppliers may not be able to deliver raw materials to our specifications. In addition, some such suppliers normally support 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, which could have a material adverse impact on our business.

We are subject to significant regulatory oversight with respect to manufacturing our 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 fails to provide sufficient quality assurance or control, approval continue delivery of our commercial product or to commercialize our product candidates may not be granted. Inspections by regulatory authorities may occur at any time during the development or commercialization phase of products. 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 influence the ability of our third-party manufacturers or suppliers to fulfill their supply obligations, impacting or delaying supply or delaying programs.

The manufacturing process for any products that is subject to the FDA's, the EMA's and other regulatory authorities' approval processes, and we may need to contract with manufacturers who 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. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including 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. Our potential future dependence upon others for the manufacture of our products, product candidates and raw materials may adversely affect our future profit margins 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. 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 also are required to register ongoing clinical trials and post the results of completed clinical trials on a 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.

46
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 also are 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;
- have 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 regulatory authority 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 may be exacerbated by the COVID-19 pandemic currently affecting the global community and the global economy.
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 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 product candidates. We expect to enter into additional collaborations to access additional funding, capabilities and 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 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 violate 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 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. In addition, in general our collaborators have the right to terminate their agreements with us for convenience. 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 RibotriTapeutics, Inc., to patents 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 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 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, we also rely on outside vendors to manufacture supplies and process our product candidates. We have only recently begun to manufacture our COVID-19 vaccine on a commercial scale and may not be able to achieve commercial-scale manufacturing and processing for our 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. 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.

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 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.

51
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 United States and abroad 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 product candidates and proprietary technologies and mode 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 (for example, the COVID-19 pandemic), 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 international 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. 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 inventors, 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 parties 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 duration of the patent protection of our technology and product candidates. If any of our owned or 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 product candidates and other technology and any products or product candidates and technology we 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 have already obtained patents, and have filed and will continue to file patent applications claiming inventions in the fields in the United States and abroad. This may limit, interfere with or eliminate our ability 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 InNeST product candidates, and whose claims recite steps relating to neoantigen selection. While the patent was upheld through the opposition proceedings, one of the opposing parties has appealed that decision.

Additionally, with regard to COVID-19 vaccines, we are currently a party to litigations. Agenus Pharmaceuticals Inc. has brought litigation against us and Pfizer regarding the ‘933 and ‘979 Patents. In addition, CureVac N.V. 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. 11,155,312, 11,149,278 and 11,241,493 that are “European counterparts” to the CureVac IP. 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, and initiated cancellation actions against the CureVac IP in the German Patent and Trademark Office. ModernaTX, Inc. has brought litigation against us and Pfizer regarding European patents 3590949B1 and 3718565B1 in Germany, England and Wales and the Netherlands, 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’122 and EP’668 Patents in the Business and Property Courts of England and Wales. Additionally, Moderna has been named as a defendant in other ongoing COVID-19 vaccine patent lawsuits. We cannot guarantee that we will not become subject to additional 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 foreign 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, our intellectual property rights. Our defense against attempts 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, 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 pipeline may involve additional product candidates 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 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.

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 condition, 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 lifespan 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 foreign 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.

58
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 the obligations owed or amounts payable under our agreements. For example, we are currently in discussions regarding amounts payable by us under our license agreement with the NIH. Any failure to satisfy obligations or any material breach under any of our licenses to third-party intellectual or any disagreements between us and our licensors could potentially give a licensor the right or reason to terminate the license or 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, which could prevent us from developing, 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 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. 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.
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, Genevant, and Cellscript, have been generated through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, 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 of these inventions or produced through the use of any of these 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 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 condition, 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 COVID-19 vaccine, or that used in our inSXT 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 candidate(s), 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, our COVID-19 vaccine was granted full FDA approval for individuals 12 years of age and older on August 23, 2021 (after BLA submission on May 18, 2021) and emergency use authorization for individuals 6 months to less than 12 years of age, after both of which 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 one or more 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 our 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 or not available on commercially reasonable terms or at all, and design-around could be prohibitive, expensive or impossible.

Additionally, with respect to our COVID-19 vaccine and our other potential COVID-19 vaccine candidates and related technologies, it is unclear whether the U.S. government, or other governments around the world, will protect vaccine manufacturers for liability from infringement of third party intellectual property, at least during the period of the pandemic. 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 is deemed protected from infringement during the period of pandemic crisis, once that period has passed, or as otherwise might be established, 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.

61
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 product 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 parties 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 parties review proceedings against issued U.S. patents and opposition proceedings against European patents owned by third parties. We have a number of these 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 number 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 product candidates 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, certain of our wholly owned subsidiaries are defendants in litigations initiated by CureVac AG, Alnylam Pharmaceuticals, Inc., and ModernaTX, Inc. regarding Comirnity. 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
competing 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 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 litigation or 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 litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or 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 reasonable 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, it could have a material adverse effect on the price of the ADSs.
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 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 or 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.

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.

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
terribly 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, 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 successful, may give rise to disputes over such distribution principles or over proper treatment of such distribution of 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 and consultants 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 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 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.
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, 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 our trademarks and trade names may jeopardize our rights in or diminish the goodwill associated with our trademarks. In addition, there could be potential trademark or trade name infringement claims brought by owners of other trademarks or trade names that incorporate variations of our trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks, trade names, trade secrets, know-how, domain names, copyrights or other intellectual property, we may not be able to compete effectively and our business, financial condition, results of operations and prospects 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 our trademarks and trade names may jeopardize our rights in or diminish the goodwill associated with our trademarks.

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-marked approval, or PMA, for the 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 Européenne 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 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 countries 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 marketing 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 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 a 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 Biologies 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 approve 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, integrate into cell DNA, or otherwise make any permanent changes to cell DNA. Consequently, we expect that our 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 product candidates to address safety concerns that are not available to all gene therapies, such as lowering the dose of our 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. Specifically, in Japan, the Pharmaceuticals and Medical Devices Agency has not taken a position on the regulatory classification. 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 clinical hold on gene therapy products across the field due to risks associated with altering cell DNA irreversibly may apply to our mRNA product candidates irrespective of the mechanistic differences between gene therapies and mRNA.

71
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 mRNA 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 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 counties, 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 these 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 international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

A third-party investigational drug 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 drugs. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, 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 therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies 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 therapies 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 therapy if that unapproved therapy does not ultimately obtain marketing approval. In addition, unapproved therapies 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 drugs or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the drugs 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 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 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 product candidates cause undesirable side effects, it could delay or prevent their regulatory approval, limit the commercial potential, or result in significant negative consequences following any potential marketing approval. 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 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 each product candidate 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.

If we are successful in gaining approval for any of our product candidates, we will continue to face significant regulatory oversight of the manufacturing and distribution of our products. 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.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will 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 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 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 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;

75
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;

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. 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 not complied with any of these laws, we may be subject 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 breaches. 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 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 that are developing potential therapeutics and vaccines to combat COVID-19, including BioNTech SE, 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. For example, during 2022 the closing sales price of the ADSs representing our ordinary shares on the Nasdaq Global Select Market ranged from $118.43 to $231.85, with significant volatility occurring shortly after announcements related to regulatory and purchase announcements related to our COVID-19 vaccine and to other COVID-19 vaccines. Additionally, we have observed the trading price of the ADSs respond significantly to news and statements by us, government agencies, competing vaccine developers, financial analysts or others relating to other COVID-19 vaccines and COVID-19 therapeutics and the pandemic generally, even in cases in which we believe the news does not affect our business or vaccine specifically.

Given the attention being paid to the COVID-19 pandemic 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 that, as a result, the price of the ADSs representing our ordinary shares likely will continue to be volatile.

**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 January 2023, we announced an agreement to acquire InstaDeep Ltd. (“InstaDeep”), a leading global technology company in the field of artificial intelligence and machine learning, for upfront consideration of cash and BioNTech shares, and potential future milestone payments. 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.

79
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 in 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 is 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 our ADS repurchase program 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 our repurchase plan. These purposes 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 our ADS repurchase program. We are not obligated to repurchase any specific amount of ADSs, and the ADS repurchase program may be suspended or terminated at any time. Additionally, because we have entered into a Rule 10b5-1 trading plan governing the repurchases, we have no discretion over the particular sales made and are only 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, 2022, 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 to 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 a registration statement 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 and any other registration statements on Form S-8 we file in the future 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 included 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.

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. American Depositary Shares (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 process in the United States is c/o BioNTech US Inc., 40 Erie Street, Suite 110, Cambridge, Massachusetts 02139, +1 (617) 237-4701.
B. Business Overview

1. 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 need and major global health burden.

Our fully integrated model combines decades of research in immunology, translational drug discovery and development, a technology agnostic innovation engine, GMP manufacturing, and commercial capabilities to rapidly discover, develop and commercialize our marketed products and other candidate vaccines and therapies.

We have built a broad toolkit across multiple technology platforms, including a diverse range of potentially first-in-class therapeutic approaches. This includes mRNA vaccines and therapeutics, cell and gene therapies, targeted antibodies and small molecule immunomodulators.

Our approach has created a robust and diversified product pipeline across infectious disease and oncology, including Comirnaty, our COVID-19 vaccine and first marketed product, over 25 clinical stage product candidates and more than 30 research projects.

In 2022, we executed on five key strategic objectives to strengthen our technology platforms, digital capabilities, and infrastructure through sustainable investments, strategic partnerships and tactical acquisitions to bring long-term value to patients and other stakeholder groups.

1. Further COVID-19 vaccine launches
   We and Pfizer developed and launched two Original/Omicron-adapted bivalent vaccines, expanded Comirnaty’s label to include pediatrics and other populations for primary and booster vaccination, converted conditional or emergency approvals to full marketing authorizations, and between us invoiced sales of approximately 2 billion doses of Comirnaty.

2. Accelerate pipeline development
   We started five first-in-human clinical trials in oncology, including for product candidates from our off-the-shelf mRNA vaccine platform (FixVac), mRNA-encoded antibodies (RiboMabs), and targeted antibodies. We reported clinical data updates for multiple oncology programs, including:
   - BNT122 or iNeST, our individualized cancer vaccine program in collaboration with Genentech, Inc., a member of the Roche group, or Genentech;
   - BNT113, a FixVac program;
   - BNT211, our first CARVac program, using our CARVac (CAR-T-cell Amplifying RNA Vaccine) mRNA-based immune booster; and
   - BNT312, a bispecific antibody we are co-developing in collaboration with Genmab A/S, or Genmab.

   In infectious diseases, we started five Phase 1 clinical trials, which include two next-generation COVID-19 vaccine candidates and vaccine candidates against shingles, malaria, and HSV-2 infection.

3. Ramp up R&D investments
   We expanded our team by more than 1,500 to over 4,500 employees globally by attracting top talent, including clinical and regulatory experts needed to rapidly advance our pipeline. Our diverse workforce now represents more than 80 nations and we have established subsidiaries across 5 continents.

4. Pursue complimentary acquisitions and collaborations
   We announced multiple complimentary acquisitions and collaborations including:
   - A global discovery collaboration with Crescendo Biologics Ltd to develop precision immunotherapies against targets selected by us based on the company’s proprietary Humabody V\text{\textregistered} platform;
• A multi-target research collaboration and license agreement with Medigene AG to develop T-cell receptor (TCR) based immunotherapies against cancer;

• An exclusive research collaboration with Matinas Biopharma, or Matinas, to advance novel formulations for mRNA vaccines based on Matinas’ Lipid Nanocrystal (LNC) delivery platform technology;

• The expansion of our global strategic collaboration with Genmab to develop and commercialize novel immunotherapy candidates based on Genmab’s proprietary HexaBody technology platform;

• A multi-target research collaboration with Ryvu Therapeutics S.A., or Ryvu, to develop and commercialize immuno-modulatory small molecule candidates as well as standalone small molecules from Ryvu’s STING agonist portfolio; and

• In 2023, we announced an agreement to acquire our long-time strategic collaboration partner, InstaDeep, subject to customary closing conditions, which on closing would enable us to create a fully integrated, enterprise-wide capability that leverages artificial intelligence (AI) and machine learning technologies across our therapeutic platforms and operations.

• In March 2023, we entered into an exclusive worldwide licensing agreement with OncoC4 to co-develop and commercialize ONC-392, an anti-CTLA-4 monoclonal antibody as monotherapy or combination therapy in various cancer indications. We and OncoC4 plan to start a Phase 3 trial (NCT05671510) of ONC-392 as monotherapy treatment in non-small cell lung cancer (NSCLC) patients who progress after PD-1/PD-L1 treatment in 2023. The transaction is expected to close in the first half of 2023, subject to customary closing conditions and regulatory clearance.

5. Expand global organization

In 2022, we expanded our organization in Asia, Africa, the U.S., Australasia and Europe and increased our overall R&D and production capabilities. We completed construction of a plasmid DNA manufacturing facility in Marburg, Germany, acquired a GMP-certified manufacturing facility in Singapore, and broke ground on our first turnkey mRNA manufacturing solution, or BioNTainer, in Kigali, Rwanda.

II. The BioNTech Approach

We are focused on developing next-generation immunotherapies by employing a multi-platform strategy, powered by a technology agnostic approach rooted in decades of research in immunology coupled with expertise in emerging technologies in mRNA and synthetic biology. With the approval of our COVID-19 vaccine, we believe that we have entered into a new era of mRNA technology as a drug class. We aim to build novel platforms with the ability to produce multiple product candidates. We aim to drive this transformation by applying the following principles:

• Exploiting the full potential of the immune system. Our broad pipeline includes mRNA-based vaccines, including cancer vaccines, antigen-specific tolerance vaccines and prophylactic infectious disease vaccines. In addition, it comprises mRNA-based immune activators, antigen-targeting T cells and antibodies, and defined immunomodulators of various immune cell mechanisms. This portfolio is designed to mirror the evolution of the immune system to rely on multiple complementary pathways and enable individualized treatment.

• Advancing programs to combat major health burdens. Our infectious disease product strategy is rooted in our global social responsibility and we aim to help democratize global access to mRNA medicines. Our infectious disease toolkit includes multiple technology platforms, including mRNA vaccines, prophylactic infectious disease vaccines, and a new class of precision anti-bacterials, Lysins.

• Broadening the range of patients benefiting from cancer immunotherapy. We discover and seek to exploit novel targets and target combinations. Our aim is to extend the utility of immunotherapy to patient populations that are not currently amenable or do not benefit from the targets of current immunotherapies.

• Improving the success rate. We engineer and develop highly potent drug candidates designed to be precise for the specific target. We further augment activity and counteract resistance mechanisms by combining compounds with non-overlapping, synergistic mechanisms of action, such as combining our FixVac immunotherapy, CARVac, with our novel CAR-T therapies.

• Focusing on therapeutic and individualized approaches. The root cause of recurrence or lack of tumor eradication is interindividual variability and cancer heterogeneity. Addressing this biological reality is one of the mandatory design aspects of the product candidates we develop. For example, each of our cancer immunotherapies incorporates multiple targets in order to account for this variability.
We have applied these guiding principles to a broad suite of pharmaceutical platforms, each of which is designed with the following goals: a distinct mode of action, high precision targeting, high potency and therapeutic or prophylactic potential. We expect each platform to yield a pipeline of product candidates for further development. With this technology-agnostic combination of platforms and product candidates, we believe we are pioneers in the field of individualized, patient-centric therapeutic approaches in oncology and infectious diseases today, and aim to be in other disease areas in the future.

Our Disruptive Technology Toolkit to Fight Human Diseases

1 mRNA encoded cancer-targeting antibodies and cytokines

Our current immunotherapy product candidates that are being tested in clinical trials span four distinct drug classes:

- **mRNA Vaccines and Therapeutics.** We utilize mRNA to deliver nucleic acid messages to cells, where such information is used to express proteins for pharmacological effect. In infectious disease, we are developing mRNA-based prophylactic vaccines to address COVID-19, shingles, malaria, tuberculosis, HSV-2, and other infectious diseases. In oncology, we are developing a portfolio of mRNA-based therapeutics to treat cancer, including FixVac, InST in collaboration with Genentech, and mRNA encoded cytokines and antibodies, or antibacterials.

- **Cell Therapies.** We are developing a range of cell therapies against solid tumors, including CAR-T cell therapies, neoantigen-based T-cell therapies and TCR therapies, in which the patient’s T cells are modified or primed to target cancer-specific antigens. We are also combining our mRNA FixVac platform with our first CAR-T product candidate to enhance the persistence of CAR-T cells in vivo.

- **Antibodies.** In addition to our mRNA-based antibacterials, we are developing targeted antibodies utilizing our in-house capabilities, and are developing next-generation antibodies, in collaboration with Genmab, that are designed to modulate the patient’s immune response to cancer.

- **Small Molecule Immunomodulators.** We aim to use small molecules to augment the activity of other drug classes by inducing specific and discrete patterns of immunomodulation. The first program is a small molecule toll-like receptor 7, or TLR7, immunomodulator for the treatment of solid tumors.

Across these four drug classes we have a robust clinical pipeline of 20 product candidates in oncology and 6 product candidates in infectious disease. We plan to accelerate the build-out of our oncology commercial capabilities in 2023-24 with the goal of commercial readiness in the United States, European Union and other selected regions to support first oncology launches from 2026 onwards. Longer-term, we see applications for our technologies in the fields of autoimmune diseases, inflammatory diseases, cardiovascular diseases, neurodegenerative diseases, and regenerative medicines.

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

Our first 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 2022, our original COVID-19 vaccine product has been authorized or approved for emergency or temporary use or granted marketing authorization in more than 100 countries and regions worldwide and our efforts have resulted in more than 4 billion doses shipped globally.
Under our collaboration with Pfizer, we are the Marketing Authorization Holder in the U.S., the European Union, the United Kingdom, Canada and other countries, and the holder of emergency use authorizations or equivalents in the U.S. (jointly with Pfizer) and other countries. Pfizer has marketing and distribution rights worldwide with the exception of China, Germany, and Turkey. Fosun Pharmaceutical Industrial Development, Co., Ltd, or Fosun Pharma, has marketing and distribution rights in Mainland China, Hong Kong Special Administrative Region, or SAR, Macau SAR and the region of Taiwan. We have the marketing and distribution rights to Comirnaty in Germany and Turkey.

1. Commercial Update

In 2022, we and Pfizer continued our global COVID-19 vaccine leadership with the first-to-market Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine directed against both the original COVID-19 virus and the Omicron BA.4-5 adapted COVID-19 virus. We now have three commercial COVID-19 vaccine products on the market: the original COVID-19 vaccine, and two Original/Omicron-adapted bivalent vaccines: Original/BA.1- and Original/Omicron BA.4-5-adapted bivalent vaccines, which are all referred to as Comirnaty.

In 2022, together with Pfizer, we invoiced approximately two billion doses of Comirnaty. As part of our and Pfizer’s two-billion-doses pledge to support equitable access to medicines, we and Pfizer have delivered approximately 1.7 billion doses of Comirnaty to low- and middle-income countries in line with demand.

In June 2022, Pfizer entered into a new vaccine supply agreement with the U.S. government. Under the terms of the agreement, the U.S. government received 105 million doses, including 30 µg, 10 µg and 3 µg doses, including the Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine for adults. The U.S. government also has the option to purchase up to an additional 195 million doses, bringing the potential total to 300 million vaccine doses. Delivery of the vaccine doses began in late summer 2022. The U.S. government was contractually required to pay the two companies $3.2 billion after receiving the first 105 million doses of vaccine.

In September 2022, following regulatory approvals, we and Pfizer began shipping Original/Omicron BA.1- and BA.4-5-adapted bivalent COVID-19 vaccines in time for fall and winter booster campaigns. Shipments to the U.S. began approximately two months after the FDA provided its guidance for the Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccines. As of mid-December 2022, we and Pfizer have shipped approximately 350 million doses of Original/Omicron-adapted bivalent vaccine.

In December 2022, we and Fosun Pharma provided approximately 11,500 doses of Comirnaty which were delivered to Mainland China to enable a vaccination campaign for German expatriates. The delivery contained both the Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine and the original COVID-19 vaccine.

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, there will be continued vaccine boosting and vaccinations of immunologically naive populations. To meet this need, in 2023, we plan to deliver doses originally scheduled for delivery in 2022 in some geographies. We also expect that in 2023, some governments will no longer be the main COVID-19 vaccine purchasers for their populations, and that commercial buyers will assume that role. In the U.S., for example, we expect that shift to happen in the third quarter of 2023.

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. More details on our manufacturing operations and facilities can be found in “VII. Manufacturing.”
3. Clinical Development

Original COVID-19 vaccine

In April 2022, we and Pfizer announced positive results from a Phase 2/3 clinical trial evaluating the safety, tolerability and immunogenicity of a 10-µg booster (third) dose of the original COVID-19 vaccine administered approximately six months after the second dose of the original COVID-19 vaccine in 140 healthy children 5 through 11 years of age:

- These data demonstrate an increase in SARS-CoV-2 Omicron variant and original strain neutralizing titers following a booster dose of the original COVID-19 vaccine compared to two doses.
- Data from a sub-analysis of 30 sera from this study indicate that serum antibodies induced by a third dose neutralize the SARS-CoV-2 Omicron variant in this age group, as demonstrated by a 36-fold increase in neutralizing antibody titers compared to levels seen after two doses of the original COVID-19 vaccine.
- Immunogenicity data from participants who had no evidence of prior SARS-CoV-2 infection showed a 6-fold increase (95% CI: 5.0, 7.6) in SARS-CoV-2 original strain–neutralizing geometric mean titers (GMTs) one month after the booster compared to the SARS-CoV-2–neutralizing GMTs one month after the second dose of the primary series of the original COVID-19 vaccine. A robust response was observed regardless of prior SARS-CoV-2 infection.
- The third dose was well tolerated, with a safety profile similar to the two-dose primary series.

In May 2022, we and Pfizer announced top-line safety, immunogenicity and vaccine efficacy data from a Phase 2/3 trial evaluating a third 3-µg dose of our original COVID-19 vaccine in 1,678 children 6 months through 4 years of age.

- Following a third dose the vaccine was found to elicit a strong immune response, with a favorable safety profile similar to placebo.
- Vaccine efficacy was 80.3% in children 6 months to under 5 years of age. This descriptive analysis was based on 10 symptomatic COVID-19 cases identified from seven days after the third dose and accrued as of April 29, 2022.

In August 2022, we and Pfizer announced updated efficacy data from a Phase 2/3 trial evaluating a three 3-µg dose series of the original COVID-19 vaccine in children 6 months through 4 years of age, reinforcing previously reported interim vaccine efficacy data collected in March and April 2022.

- Vaccine efficacy was 73.2% without evidence of prior COVID-19 infection. This analysis was based on 13 cases in the Pfizer-BioNTech COVID-19 vaccine group (n=794) and 21 cases in the placebo group (n=351), diagnosed from March to June 2022.
- Sequencing of observed COVID-19 cases confirmed the majority were caused by Omicron BA.2, consistent with the time period when the cases occurred, broadening the evidence for efficacy across COVID-19 variants.

Adapted bivalent vaccines

In January 2022, we and Pfizer initiated a clinical study to evaluate the safety, tolerability and immunogenicity of three different regimens of the Omicron BA.1-adapted vaccine candidate or the original COVID-19 vaccine in healthy adults 18 through 55 years of age. The study also drew upon some participants from the companies’ Phase 3 COVID-19 booster study.

In June 2022, clinical data from this Phase 2/3 trial showed that a booster dose of our and Pfizer’s Original/Omicron BA.1-adapted bivalent vaccine elicited a superior immune response against the Omicron BA.1 sublineage compared to the original vaccine.

Also in June 2022, the U.S. FDA advised vaccine manufacturers to develop modified vaccines that add an Omicron BA.4-5 spike protein encoding component to the original vaccine composition to create a bivalent booster vaccine. In less than three months after the FDA provided its guidelines for adapted vaccines in the U.S., we were ready to ship the first doses of our Omicron BA.4-5 adapted bivalent vaccine.
In October 2022, we and Pfizer reported data from a randomized Phase 2/3 trial evaluating the safety, tolerability, and immunogenicity of the Original/Omicron BA.4-5-adapted bivalent vaccine in individuals aged 12 years and older.

- A 30-µg booster demonstrated a substantial increase in the Omicron BA.5 neutralizing antibody response above pre-booster levels based on sera taken seven days after administration, with similar responses seen across individuals aged 18 to 55 years and those older than 55 years of age (40 participants in each age group).
- The Original/Omicron BA.4-5-adapted bivalent vaccine was well tolerated, with early data indicating a favorable safety profile similar to that of the original vaccine.

In September 2022, we and Pfizer initiated a Phase 1/2/3 study to evaluate the safety, tolerability and immunogenicity of different doses and dosing regimens of the Original/Omicron BA.4-5-adapted bivalent vaccine in children 6 months through 11 years of age. This pediatric study follows a previous Phase 1/2/3 trial in these age groups that demonstrated the original vaccine is well-tolerated and offers a high level of protection against COVID-19, measured at a time when the Omicron BA.2 strain was highly prevalent.

In November 2022, we and Pfizer announced results from an analysis examining the immune response induced by the Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine against newer Omicron sublineages, including BA.4.6, BA.2.75.2, BQ.1.1 and XBB.1.

- These data indicate that the bivalent vaccine elicits a greater increase in neutralizing antibody titers than the original COVID-19 vaccine against these emerging Omicron sublineages. One month after a 30-µg booster dose of the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine, neutralizing antibody titers against emerging Omicron sublineages increased 3.2- to 4.8-fold compared to the companies' Original COVID-19 vaccine.
- Neutralizing antibody titers against Omicron sublineages BA.4.6, BA.2.75.2, BQ.1.1, and XBB.1 increased 4.8- to 11.1-fold from pre-booster levels following a 30-µg booster dose of the Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine.
4. Regulatory Updates

In 2022, our and Pfizer’s COVID-19 vaccine received multiple regulatory approvals and authorizations, including for Original/Omicron-adapted bivalent vaccines, label expansions for pediatric vaccinations and ongoing conversions from conditional or emergency approvals or authorizations to full regulatory approvals worldwide. Our and Pfizer’s Original/Omicron BA.4-5-adapted bivalent vaccine has received approvals, authorizations for emergency or temporary use, or marketing authorizations in more than 65 countries and regions in 2022.

**COVID-19 Vaccine Approvals and authorizations in Europe and the U.S.**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>January</td>
<td>U.S. FDA expanded EUA of a booster dose (30 µg) of the original COVID-19 vaccine to include individuals 12 years of age and older.</td>
</tr>
<tr>
<td>February</td>
<td>EC approval of the administration of the companies’ original COVID-19 vaccine as a booster dose (30 µg) at least six months after the second dose in adolescents 12 through 17 years of age.</td>
</tr>
<tr>
<td>February</td>
<td>EU Product Information of Comirnaty was updated to include the use of the vaccine during pregnancy.</td>
</tr>
<tr>
<td>March</td>
<td>U.S. FDA expanded EUA of the original COVID-19 vaccine to include a second booster dose in adults ages 50 years and older who have previously received a first booster of any authorized COVID-19 vaccine. The FDA also authorized a second booster dose for individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise and who have received a first booster dose of any authorized COVID-19 vaccine.</td>
</tr>
<tr>
<td>May</td>
<td>U.S. FDA expanded EUA to include a booster dose (10 µg) after completion of the primary series of the original COVID-19 vaccine in children 5 through 11 years of age.</td>
</tr>
<tr>
<td>May</td>
<td>EC approved the reduction of the interval between the primary course and booster vaccination from six months to three months in individuals 12 years of age and older.</td>
</tr>
<tr>
<td>June</td>
<td>U.S. FDA granted EUA of the original COVID-19 vaccine as a three 3-µg dose series for children 6 months through 4 years of age (also referred to as 6 months to less than 5 years of age).</td>
</tr>
<tr>
<td>July</td>
<td>U.S. FDA approved the supplemental Biologics License Application (BLA) to include individuals 12 through 15 years of age in the approved indication.</td>
</tr>
</tbody>
</table>
September: EC approval of 10-µg booster (third) dose of the original vaccine given at least 6 months after completion of a primary series for children 5 through 11 years of age.

October: EC approval for the conversion of the conditional Marketing Authorization (CMA) to full Marketing Authorization (MA). The conversion applies to all existing indications and formulations of the Comirnaty product group authorized in the EU, including Original/Omicron BA.1- and BA.4-5-adapted bivalent vaccines as booster doses for individuals aged 12 years and older.

October: EC approval for full MA for a 3-µg dose of the original COVID-19 vaccine as a three-dose series for children aged 6 months through four years.

October: EC approval for a fourth dose booster of the original COVID-19 vaccine in individuals 12 years of age and older at an interval of at least three months between the administration of the original COVID-19 vaccine and the last prior dose of a COVID-19 vaccine.

Adapted bivalent vaccine
In 2022, we and Pfizer received the following approvals and authorizations for our adapted COVID-19 vaccines:

• Approval or authorizations of a 30-µg booster dose of the Original/Omicron BA.4-5-adapted bivalent vaccine for individuals aged 12 years and older was granted by the U.S. FDA (August), EC (September), Health Canada (October), and Health Bureau of the Hong Kong Special Administrative Region of the People’s Republic of China (November).

• September: EC approval for a 30-µg booster dose of the Original/Omicron BA.1-adapted bivalent vaccine for individuals aged 12 years and older.

• Approval or authorizations of 10-µg booster dose of Original/Omicron BA.4-5-adapted bivalent vaccine in children 5 through 11 years of age was granted by U.S. FDA (EUA) (October) and EC (November).

• December: U.S. FDA EUA for our Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine as the third 3-µg dose in the three-dose primary series for children 6 months through 4 years of age.

• December: full regulatory approval (BLA) of our 30-µg original COVID-19 vaccine as well as of a 30-µg booster dose of our Original/Omicron BA.4-5-adapted bivalent vaccine in individuals 12 years and older in Hong Kong.

IV. 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.

Infectious disease pipeline

The Covid-19 influenza combination is a Phase 1 trial in partnership with Pfizer. Further development is subject to reaching agreement.
A. Oncology Programs

There were an estimated 18.1 million new cancer cases around the world in 2018, with nearly 9.5 million deaths. Early and appropriate diagnosis is essential for appropriate and effective treatment because every cancer type requires specific treatment. Heterogeneity (somatic mutations), the tumor environment and immune diversity make cancer an extremely complex and heterogeneous disease. Our diverse toolkit of different technologies and modes of action has potential to address a broad range of solid tumors in different disease stages. Our immuno-oncology strategy is based on pioneering approaches to harness the immune response to treat cancer. We have multiple clinical stage assets across different therapeutic classes and platforms which have the potential to tackle tumors using complementary strategies, either by targeting tumor cells directly, or by modulating the immune response against the tumor.

1. mRNA Product Class in Oncology

a) FixVac

- Concept: Cancer immunotherapies targeting shared antigens that we have identified to be frequently expressed across patients with a specific cancer type.
- mRNA Format: Optimized uridine-containing mRNA.
- mRNA Delivery Formulation: Proprietary RNA-LPX, designed to deliver RNA to dendritic cells (DCs).
- Development Approach: Worldwide rights; wholly owned.

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. Our FixVac product candidates leverage our uridine mRNA (uRNA) technology to prime T cells and booster T-cell immunity against common tumor-specific non-mutated antigens, resulting in a strong antigen-specific immune response.

FixVac product candidates feature our immunogenic mRNA backbone and proprietary RNA-LPX delivery formulation for intravenous administration, which are designed to trigger both innate and adaptive immune responses and may be of clinical utility in combination with anti-PD1 in patients with lower mutational burden tumors, including those who have already experienced checkpoint inhibitor, or CPI, therapy.
Melanoma remains one of the deadliest types of skin cancer with a 5-year survival for Stage IV metastatic disease of only 27%. In refractory or relapsed setting, survival can be as short as six months depending on risk factors. Up to 50% of patients progress after treatment with checkpoint inhibitors. We are currently studying BNT111 for the potential treatment of advanced melanoma in a randomized Phase 2 clinical trial in combination with Regeneron’s anti-PD1 therapy, LIBTAYO (cemiplimab). An additional Phase 1 trial is ongoing.

**BNT111 Targets**

BNT111 is designed to elicit an immune response to the following four antigens that have each been found to be associated with melanoma:

- New York esophageal squamous cell carcinoma 1, or NY-ESO-1, a well-known cancer-testis antigen that is also expressed in numerous cancers, including melanoma;
- Melanoma-associated antigen A3, or MAGE-A3, which is not expressed in normal tissues, except the testis;
- Tyrosinase, an enzyme that is required for melanin production and that is expressed at high levels in melanoma; and
- Trans-membrane phosphatase with tensin homology, or TPTE, a novel cancer/testis antigen that we discovered internally.

Sequencing data from 337 melanoma tumors showed that at least one of these four antigens is detected in over 90% of such melanoma tumors.

BNT111 antigens detected in over 90% of melanoma tumors. The graphic above shows expression of BNT111 target antigens on a patient by patient basis. Each row at the bottom of the graphic represents an antigen, and each vertical line represents a patient, depicting whether or not that patient’s tumor expressed each antigen. Red/yellow = antigen is expressed in patient’s tumor; white = no expression.
BNT111 Clinical Trials

**Ongoing Phase 2 Trial with anti-PD-1 Therapy**

A global, randomized three-arm Phase 2 trial evaluating BNT111 in combination with cemiplimab (Regeneron’s Libtayo) versus both agents as monotherapy in 180 patients with anti-PD-1/-PD-L1 refractory-relapsed, unresectable Stage III or IV melanoma is ongoing.

- The primary endpoint is overall response rate of BNT111 in combination with cemiplimab.
- Secondary endpoints include overall response rate in the single agent arms, duration of response, and safety.

In 2021, we received from the FDA both Fast Track Designation for BNT111 in combination with cemiplimab in patients with anti-PD-1-refractory/relapsed, unresectable Stage III or IV melanoma and Orphan Drug Designation for the treatment of stage IIB through IV melanoma.

**Ongoing Phase 1 Trial (Lipo-MERIT trial)**

A multi-center, open-label, first-in-human, Phase 1 dose escalation study evaluating the safety and tolerability of multiple intravenous administrations of BNT111 in patients with advanced melanoma is ongoing. This was the first clinical trial worldwide in which an mRNA-based cancer immunotherapy is administered intravenously for systemic treatment.

- The trial employed a conventional 3+3 design in which patients were dosed in groups of three at incrementally greater dosages until the maximum tolerated dose was identified, during the dose escalation phase, which was then followed by expanded dose cohorts. Patients were treated with doses from 7.2µg up to the highest administered dose of 400µg of total RNA.
- Data from an exploratory interim analysis of the Lipo-MERIT trial was published in *Nature* in 2020, and a data update from the ongoing trial was presented at the Society of Immunotherapy of Cancer (SITC) Annual Meeting in 2021.

**ii. BNT112 for the Treatment of Prostate Cancer**

BNT112 is currently being studied in an ongoing Phase 1/2a clinical trial.

Our BNT112 Targets

BNT112 is designed to elicit an immune response to five prostate cancer-specific antigens, 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.

**BNT112 Clinical Trial**

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

PRO-MERIT, a first-in-human, Phase 1/2a open-label dose titration and expansion trial to evaluate safety, immunogenicity and preliminary efficacy of BNT112 monotherapy and in combination with cemiplimab in patients with metastatic castration resistant prostate cancer (mCRPC) and high-risk localized prostate (LPC) who are eligible for treatment with androgen deprivation therapy (ADT) followed by radical prostatectomy is ongoing.

- Part 1 is a first-in-human, single arm design for mCRPC patients.
- Part 2 consists of four arms (1A, 1B, 2 and 3), with similar intra-patient dose titration in Cycle 1, for both mCRPC and LPC indications, and targeting to enroll approximately 106 patients. Arms 1A and 1B are designed to treat mCRPC patients with a combination treatment (BNT112 and cemiplimab) and monotherapy (BNT112), respectively. Arms 2 and 3 are designed to treat LPC patients with a combination treatment (BNT112 and cemiplimab) and monotherapy (BNT112), respectively, plus a background medication of an androgen-deprivation therapy (e.g. goserelin acetate).
- Data were presented for nine patients in Part 1 and for five patients in Part 2 at the 2021 SITC Annual Meeting.
iii. BNT113 for the Treatment of HPV16+ Head and Neck Cancer

We are currently studying BNT113 in a randomized Phase 2 clinical in combination with pembrolizumab as a first-line treatment in patients with unresectable recurrent or metastatic HPV16+ head and neck squamous cell carcinoma, or HNSCC, expressing PD-L1. An additional investigator sponsored Phase 1/2 basket trial is ongoing.

**Our BNT113 Targets**

BNT113 encodes 2 oncoproteins exclusively expressed in pre-malignant and malignant tissue. HPV-associated cancers are increasing, with HPV16+ HNSCC typically occurring in younger people. 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.

**BNT113 Clinical Trials**

**Overview BNT113 Phase 2 Trial**

A global randomized Phase 2 trial evaluating BNT113 in combination with pembrolizumab 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 (Part A) designed to demonstrate the safety of the combination of BNT113 and pembrolizumab.
- Part B is randomized and is planned to enroll a total of 267 patients.
- Primary endpoints include overall survival and objective response rate.
- Secondary endpoints include progression free survival, durable complete responses, duration of response, patient reported outcomes and quality of life measures.

In December 2022, we presented preliminary safety data from Part A of the trial at the ESMO Immuno-Oncology Annual Congress. The data showed safety was acceptable and in line with the safety profile of BNT113 and pembrolizumab as single agents; no new safety signals were observed for the combination.

- As of July 5, 2022, of 15 treated patients, 12 had completed the safety run-in (pembrolizumab + 4 BNT113 doses).
- All patients in the safety run-in had ≥1 AE; the most frequent were pyrexia (8 patients) and chills (8 patients).
- Three patients (25%) that had Grade ≥3 AEs with all classed as SAEs (pyrexia, hypercalcemia, pleural effusion, shaking/vigors).
- In 2/3 patients the AEs (pyrexia, shaking/vigors) were considered related.
- No deaths were reported.

**Overview Phase 1/2 Basket Trial (Investigator-Sponsored)**

BNT113 is being studied by the University of Southampton in an investigator-sponsored open-label, Phase 1/2 dose escalation basket study with two different arms in approximately 44 patients with HPV16+ head and neck and other cancers.

- The first arm will perform dose escalation in patients with previously treated HPV16+ head and neck cancer using two dose cohorts to establish a safe, tolerable and recommended dose of BNT113.
- The second arm will perform dose escalation in patients with advanced HPV16+ cancers, including head and neck, anogenital, penile and cervical cancers, using a single cohort to establish a safe, tolerable and recommended dose.

iv. BNT115 for the Treatment of Ovarian Cancer

BNT115 is currently being studied in an ongoing investigator-initiated and -sponsored Phase 1 trial.

**BNT115 Targets**

BNT115 is designed to elicit an immune response to selected antigens that are found in epithelial ovarian cancers.
BNT115 Clinical Trial
Ongoing Phase 1 Trial (Investigator-Initiated and Sponsored)

BNT115 is being studied in an investigator-initiated and sponsored first-in-human, open label, Phase 1 dose escalation 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 at this stage. The follow-up phase for enrolled patients is still being completed. The final evaluation of the clinical data from the trial will be completed by the University Medical Center Groningen, Netherlands and recorded accordingly.

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

BNT116 is being evaluated in a Phase 1 clinical trial alone and in combination with cemiplimab (anti-PD-1, Regeneron’s Libtayo) or in combination with docetaxel in patients with advanced or metastasized NSCLC.

In March 2022, we announced the expansion of our strategic collaboration with Regeneron. Under the agreement, we and Regeneron will jointly conduct trials to evaluate the combination of BNT116 and cemiplimab in different patient populations.

BNT116 Targets

BNT116 is designed to elicit an immune response to six tumor-associated antigens that cover up to 100% of patients in all major histologic subtypes of non-small cell lung cancer.

BNT116 Clinical Trials Updates

Ongoing Phase 1 Trial in NSCLC 2L+

In July 2022, the first patient was dosed in a first-in-human clinical trial evaluating the safety, tolerability and preliminary efficacy of BNT116 alone and in combination with cemiplimab (anti-PD-1, Regeneron’s Libtayo) in patients with advanced or metastasized NSCLC.

• The trial is intended to establish a safe dose for BNT116 monotherapy as well as for BNT116 in combination with cemiplimab in patients who have progressed on prior PD-1 inhibitor treatment or are not eligible for chemotherapy, and in combination with docetaxel in patients who have received prior platinum-based chemotherapy.

Planned Phase 1/2 Trial in NSCLC 1L

A second trial, sponsored by Regeneron, is planned to start in 2023 to evaluate BNT116 alone and in combination with cemiplimab (Regeneron’s Libtayo) as first-line treatment of patients with advanced NSCLC whose tumors express programmed cell death ligand-1 (PD-L1) in ≥ 50% of tumor cells.

• The primary objective of the Phase 1/2 trial is to assess the safety and tolerability as well as the objective response rate (ORR) and tumor burden reduction.

b) Individualized Neoantigen Specific Immunotherapy (iNeST)

Concept: Individualized cancer immunotherapy targeting neoantigens identified on a patient by patient basis and selected for immunogenicity.

mRNA Format: Optimized uridine-containing mRNA.

mRNA Delivery Formulation: Proprietary RNA-LPX, designed to deliver RNA to dendritic cells (DCs).

Development Approach: 50:50 cost share with Genentech.

iNeSTs are individualized cancer immunotherapies that target specific neoantigens that are present on a patient’s tumor. Our iNeST approach is also based on a pharmacologically optimized mRNA delivered in our proprietary RNA-LPX formulation. 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. We believe this modality is well-suited for use in early-stage and metastatic cancers and adjuvant setting.
i. Autogene cevumeran (BNT122) for Multiple Potential Indications

We and our collaborator Genentech are developing autogene cevumeran (BNT122) for the treatment of adjuvant and metastatic solid tumors. We and our collaborator Genentech are currently conducting a randomized Phase 2 trial of autogene cevumeran in combination with pembrolizumab in first-line melanoma. In collaboration with Genentech, we studied autogene cevumeran as a monotherapy and in combination with atezolizumab in a Phase 1a/1b study of patients with locally advanced or metastatic solid tumors (including melanoma, non-small cell lung cancer, bladder cancer as well as other solid tumors) and moved into the adjuvant treatment space with a randomized Phase 2 trial in colorectal cancer patients. An additional Phase 2 trial in the adjuvant setting in patients with pancreatic ductal adenocarcinoma (PDAC) is planned to open in 2023. An open-label Phase 1a (monotherapy)/1b (in combination with the anti-PD-L1 immune checkpoint inhibitor atezolizumab) basket trial as well as an investigator-initiated Phase 1 clinical trial in combination with atezolizumab and chemotherapy are also ongoing.

Autogene cevumeran (BNT122) Targets

Autogene cevumeran (BNT122) is an individualized neoantigen-specific immunotherapy. Each autogene cevumeran dose includes up to 20 different neoantigens selected on a patient-by-patient basis. We believe that neoantigen specific T cells induced by autogene cevumeran may be able to enhance the therapeutic efficacy of immune checkpoint blockade.

Autogene cevumeran (BNT122) Clinical Trials Update

**Ongoing Phase 2 Trial in first-line melanoma with pembrolizumab**

An open-label Phase 2 trial evaluating the efficacy and safety of autogene cevumeran in combination with pembrolizumab versus pembrolizumab alone in 126 patients with previously untreated advanced melanoma is ongoing.

- Patients in the experimental arm receive pembrolizumab by intravenous infusion every three weeks, plus a selected dose of autogene cevumeran at defined intervals. Patients in the active comparator arm receive 200 mg of pembrolizumab by intravenous infusion every three weeks. Patients in the comparator arm experiencing confirmed disease progression are permitted to cross over to combination therapy with autogene cevumeran.
- The primary endpoint is progression-free survival, or PFS, of patients treated with autogene cevumeran compared with patients receiving pembrolizumab alone, according to RECIST v1.1.
- Secondary endpoints include objective response rate, or ORR, overall survival, or OS, duration of response, or DOR, and safety. We and our collaborator, Genentech, expect a data update in 2023.

**Ongoing Phase 2 Trial in adjuvant colorectal cancer**

A randomized, multi-site, open-label Phase 2 trial 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 overall survival, or OS, and safety. The trial has been initiated in the U.S., Germany, Spain and Belgium.

**Ongoing Phase 1a/1b Clinical Trial**

An open-label Phase 1a (monotherapy)/1b (in combination with atezolizumab) trial of autogene cevumeran in patients with locally advanced or metastatic solid tumors, including patients with melanoma, non-small cell lung cancer, bladder cancer, colorectal cancer, TNBC, renal cancer, head and neck cancer and sarcomas as well as other solid tumors is ongoing. Enrollment of the trial is now completed.

- The study is designed to enroll both patients with and without prior checkpoint inhibitor regimens and included a Phase 1a (monotherapy) dose escalation, a Phase 1b (combination) dose escalation, and multiple Phase 1b expansion cohorts. Patients received nine doses of the vaccine administered I.V. in weekly and bi-weekly intervals during the 12-week induction stage and every 24 weeks during the maintenance stage. In the Phase 1b portion of the trial, atezolizumab was administered on day one of each 21-day cycle.
The primary objective of the study is to assess safety (including dose-limiting toxicities).

Additional objectives include evaluation of immunogenicity and preliminary assessment of anti-tumor activity.

Clinical Data from Phase 1 Investigator-Initiated Trial in PDAC

In June 2022, at the ASCO Annual Meeting, we presented preliminary data from an investigator-initiated Phase 1 clinical trial of autogene cevumeran in combination with the anti-PD-L1 immune checkpoint inhibitor atezolizumab and chemotherapy in patients with surgically removed pancreatic ductal adenocarcinoma (PDAC).

- The data presented include a total of 19 patients who underwent surgery and received atezolizumab. 16 out of these 19 patients (84%) received autogene cevumeran at 9.4 weeks (median; 95% CI 9–10) after surgery.
- The preliminary data readout from these 16 vaccinated patients revealed that autogene cevumeran in combination with atezolizumab was well-tolerated. Only 1 of 16 patients (6%) developed a vaccine-related Grade 3 fever and hypertension, no other Grade 3 or higher adverse events were observed.
- ELISPOT in combination with TCR expansion showed that the treatment induced de-novo, neoantigen-specific T-cell response in half (8/16) of these patients from undetectable levels to large fractions of all blood T cells (median 2.9%).
- At an early median follow-up of 18 months, patients with de-novo immune response (n=8) had a significantly longer recurrence-free survival (RFS) as compared to those without vaccine-induced immune responses (n=8) (median not reached vs. 13.4 months, HR 0.08, 95% CI 0.01-0.4, P = 0.003).

We and Genentech plan to open a randomized Phase 2 study to further evaluate the efficacy and safety of autogene cevumeran in combination with atezolizumab and chemotherapy in patients with resected PDAC in 2023.

Preliminary clinical data from autogene cevumeran monotherapy and in combination with atezolizumab in patients with solid tumors were presented at AACR in 2020 showing manageable safety profile and induction of strong neoantigen-specific immune responses. Based on published data from BNT122 and data from the study with BNT121 (a prior iNeST precursor to autogene cevumeran, published in Sahin U et al. 2017. Nature 547, 222-226.) as an adjunct to surgery in patients with metastatic melanoma, we and Genentech believe that autogene cevumeran is best suited for adjuvant and minimal residual disease settings.

c) mRNA Intratumoral Immunotherapy

- Concept: Immunomodulator-encoding mRNA injected directly into the tumor in order to avoid off-target toxicities.
- mRNA Format: Nucleoside-modified mRNA engineered for minimal immunogenicity in order to avoid immune detection and allow translation of the encoded cytokines to occur within the cells.
- mRNA Delivery Formulation: Various formulations, delivered by intratumoral injection.
- Development Approach: Co-development and co-commercialization, at our option, in collaboration with Sanofi.

We started developing intratumoral immunotherapies utilizing our proprietary mRNA technology in collaboration with Sanofi. These immunotherapies have been designed to be administered directly into the tumor in order to alter the tumor microenvironment and enhance the immune system's ability to recognize and fight cancer cells within the tumor (proximal) as well as in other non-injected tumor sites (distal).

i. BNT131 (SAR441000) for the Treatment of Solid Tumors

The immunotherapy BNT131 (SAR441000) consists of modified mRNAs encoding for immunomodulatory cytokines for direct intratumoral injection. In the tumor, the cytokine encoding mRNAs are expected to be taken up by tumor and other resident cells and translated into functional cytokine proteins which are expected to be capable to modulate the tumor microenvironment.
BNT131 (SAR441000) Targets

BNT131 (SAR441000) comprises four mRNAs encoding the cytokines IL-12sc, IL-15sushi, IFN-α and GM-CSF, that we have identified as mediators of tumor regression across different murine tumor models. By expressing these cytokines in the tumor microenvironment, the immune system may more easily recognize and fight cancer cells. Combining the cytokine encoding mRNAs with checkpoint inhibitors enhanced antitumor responses in both injected and non-injected tumors, thereby improving survival and tumor regression in mice.

BNT131 (SAR441000) Clinical Trial

Ongoing Phase 1 Clinical Trial

Sanofi, in collaboration with us, commenced a first-in-human, multi-center, open-label, Phase 1, dose escalation and expansion trial 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 have been enrolled. The trial is active and not recruiting.

• Patients are treated with weekly intratumoral administration of BNT131 (SAR441000) in the monotherapy arm or in combination with a fixed dose of 350 mg cemiplimab q3wks in the combination arm.
• Blood samples and tumor biopsies were collected to characterize the pharmacokinetic/pharmacodynamic profile of BNT131 (SAR441000), immune cell tumor infiltration and the presence of tumor proinflammatory signatures.

In 2020, at the SITC Annual Meeting, interim data were presented that suggested BNT131 (SAR44100) has a tolerable safety profile.

• 17 patients across various solid tumor types had received BNT131 (SAR44100) as a monotherapy at varying dose levels and six patients in combination therapy.
• In some patients, increase in plasma IP10 and IFN gamma and CD8+ T-cell infiltration were observed in tumor biopsies.

RiboMabs

• Concept: Antibodies encoded by mRNA and produced in the patient as an alternative to recombinant protein antibodies.
• mRNA Format: Nucleoside-modified mRNA engineered for minimal immunogenicity in order to avoid immune detection and allow translation of the encoded antibodies to occur within the cells.
• mRNA Delivery Formulation: Various liver-targeting LNP formulations, delivered intravenously, to ensure systemic availability and prolonged production of the antibody in vivo.
• Development Approach: Worldwide rights; wholly owned.

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 LNPs for intravenous delivery.

i. BNT141 for the Treatment of Solid Tumors

BNT141 is currently being studied in an ongoing Phase 1/2 trial. Our RiboMab product candidate encodes an IgG antibody which upon injection is secreted into the bloodstream.

BNT141 Targets

BNT141 is designed to target CLDN18.2, expressed in high unmet medical need tumors, including multiple epithelial solid tumors, such as gastric, biliary and pancreatic cancers.
BNT141 Clinical Trial
Ongoing Phase 1/2 trial
In January 2022, we dosed the first patient in an open-label, multi-site, Phase 1/2 dose escalation, safety, and pharmacokinetic trial of BNT141 followed by expansion cohorts in patients with CLDN18.2-positive tumors.

- The trial design consists of three parts. Part 1A will perform dose escalation as monotherapy in patients with unresectable or metastatic CLDN18.2-positive gastric cancer, gastroesophageal junction (GEJ) and esophageal cancer of the adenocarcinoma subtype, colorectal cancer, pancreatic cancer, biliary tract cancers, and mucinous ovarian cancer, for which there is no available standard therapy likely to confer clinical benefit.
- Part 1B is a dose escalation in combination with chemotherapy in patients with advanced unresectable or metastatic CLDN18.2-positive pancreatic adenocarcinoma or cholangiocarcinoma, intending to define the maximum tolerated dose (MTD) and/or RP2D of the combination.
- A subsequent Part 2 expansion in CLDN18.2 positive patients in selected cancer indications will be further defined via an amendment after careful evaluation of all available safety, PK and PD, and efficacy data generated in Parts 1A and 1B by the Safety Review Committee (SRC). Enrollment of Part 1A is ongoing.

ii. BNT142 for the Treatment of Solid Tumors

BNT142, our second RiboMab product candidate for the treatment of solid tumors, is currently being studied in an ongoing Phase 1/2a trial.

BNT142 Targets

BNT142 is designed to encode bispecific T-cell engaging antibodies that target CD3, a T-cell receptor component that plays a key role in the activation of T cells, and CLDN6, a highly specific oncofetal cell surface antigen that is found in solid tumors, such as testicular and ovarian cancers but not in normal cells.

BNT142 Clinical Trial
Ongoing Phase 1/2 trial
In July 2022, the first patient was dosed in an open-label, multi-center Phase 1/2 dose escalation trial with expansion cohorts to evaluate safety and preliminary efficacy in patients with CLDN6-positive advanced solid tumors including ovarian, endometrial, testicular, non-squamous NSCLC and Not Otherwise Specified (NOS) tumors, including rare tumors and cancers of unknown primary.

- The trial is evaluating BNT142 as monotherapy in patients that have exhausted therapy or are not eligible for standard of care therapy.
- After dose escalation, BNT142 will be evaluated in three expansion cohorts that include patients with CLDN6-positive advanced tumors.

e) RiboCytokines

- Concept: Cytokines encoded by mRNA and produced in the patient as an alternative to recombinant cytokines.
- mRNA Format: Nucleoside-modified mRNA engineered for minimal immunogenicity in order to avoid immune detection and allow translation of the encoded cytokines to occur within the cells.
- mRNA Delivery Formulation: Various liver-targeting LNP formulations, delivered intravenously, to ensure systemic availability and prolonged production of the cytokine in vivo.
- Development Approach: Worldwide rights; wholly owned.

Our RiboCytokine product candidates BNT151 and BNT152+BNT153 are nucleoside-modified mRNAs encoding human cytokines fused to human serum albumin. The modified mRNA is formulated with liver-targeting lipid nanoparticles, or LNPs, for intravenous delivery.
i. BNT151 for the Treatment of Solid Tumors

BNT151 is being studied in an ongoing Phase 1 trial.

**BNT151 Target**

BNT151 comprises our nucleoside-modified mRNA that encodes mRNA for a function-modified or optimized IL-2. IL-2 is a key cytokine in T-cell immunity, supporting the differentiation, proliferation, survival and effector functions of T cells. BNT151 is designed to stimulate T cells without triggering immunosuppression in the tumor microenvironment.

**BNT151 Clinical Trials**

**Ongoing Phase 1/2 trial**

A first-in-human, open-label, dose-escalation, multi-center Phase 1 trial evaluating BNT151 (encoding an IL-2 variant) safety, pharmacokinetics and pharmacodynamics in multiple solid tumors, including HNSCC, hepatocellular carcinoma, renal cell cancer, NSCLC, and triple-negative breast cancer (TNBC) is ongoing.

- Part 1 of the trial involves monotherapy dose escalation, in which we will enroll patients with tumors that are metastatic or unresectable with no available standard therapy likely to confer clinical benefit. The trial also plans to implement a biomarker expansion cohort with longitudinal biopsies with the goal to identify ideal drug combination partners.
- Part 2, the combined treatment dose escalation, will enroll and treat with BNT151 and potentially other combination agents, patients with different solid tumors.

ii. BNT152+BNT153 for the Treatment of Solid Tumors

**BNT152+BNT153 Targets**

BNT152+BNT153 comprise our nucleoside-modified mRNAs that encodes mRNA for cytokines IL-7 and IL-2 respectively.

**BNT152+BNT153 Clinical Trials**

**Ongoing Phase 1 Trial of BNT152+BNT153**

An open-label, multisite, first-in-human Phase 1 trial, which will evaluate the safety, pharmacokinetics and pharmacodynamics, and preliminary anti-tumor activity of a combination of BNT152 and BNT153 is ongoing. The clinical trial will enroll patients with various solid tumors that are metastatic or unresectable for whom there is no available standard therapy likely to confer clinical benefit, or patients who are not candidates for such available therapy.

- The trial consists of 2 parts with adaptive design elements. Part 1 consists of Groups A and B.
  - Group A is a BNT153 monotherapy dose escalation in patients with advanced solid malignancies until the MTD or maximum administered dose (MAD) is defined.
  - Group B is a BNT152 monotherapy dose escalation in patients with advanced solid malignancies until the MTD or optimal biological dose (OBD) is defined, whichever occurs earlier.
- Part 2 will start once MTD or MAD have been established for BNT153 and MTD or OBD for BNT152 in Part 1 and will evaluate the combination treatment of BNT152 and BNT153. Part 1A and B (monotherapy dose escalation) is ongoing.
- This trial may implement a biomarker cohort after the pharmacodynamic effect and clinical benefit of the combination therapy are observed in Part 2. The main objective of the cohort is to identify drug induced changes in tumor tissues and correlate it with changes observed in the blood. Up to 20 patients will be enrolled in the biomarker cohort.

2. Oncology Cell Therapy Product Candidates

a) Chimeric antigen receptor (CAR) T-cell therapy - CAR-T

- Concept: Second-generation CAR-T therapy designed to overcome the shortcomings of CAR-T therapy in solid tumors.
Mechanism: T cells with CARs engineered to target cancer-specific antigens, including novel antigens selected from our proprietary antigen library and administered with an mRNA-based immune booster, which we refer to as CARVac, to enhance CAR-T-cell expansion and persistence.

Development Approach: Worldwide rights; wholly owned.

BNT211 is a chimeric antigen receptor (CAR) directing T cells against the novel target CLDN6 that is tested alone and in combination with a CAR-T-cell amplifying RNA Vaccine, or CARVac, encoding CLDN6. CARVac is also based on a pharmacologically optimized sRNA backbone delivered in our proprietary RNA-LPX formulation. CLDN6 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 drive in vivo expansion of transferred CAR-T cells to increase their persistence and efficacy. BNT211 aims to overcome CAR-T-cell therapy limitations in patients with solid tumors.

i. BNT211 for the Treatment of CLDN6+ Solid Tumors

BNT211 is being studied in an ongoing Phase 1/2 trial.

BNT211 Target

BNT211 targets Claudin 6, or CLDN6, a highly specific oncofetal cell surface antigen that is expressed in multiple cancers, including ovarian, testicular and lung cancers, but not in healthy tissue.

Ongoing Phase 1/2 Clinical Trial

A Phase 1/2 open-label, multi-center dose escalation and dose expansion basket trial evaluating CLDN6 CAR-T cells with or without a CLDN6 CARVac in CLDN6-positive relapsed or refractory advanced solid tumors, including ovarian and testicular cancers, is ongoing.

- The primary outcome measure of the trial will be safety, with secondary efficacy outcome measures to include objective response rate, disease control rate and duration of response.
- The trial is run in 2 parts: Part 1 is the dose escalation of CLDN6 CAR-T cells as monotherapy.
- Part 2 is a dose escalation that combines CLDN6 CAR-T cells plus CLDN6 CARVac.

Data update from BNT211 Phase 1/2 Trial

At the ESMO Congress in September 2022, we presented encouraging follow-up data from the ongoing trial evaluating the safety and preliminary efficacy of BNT211 in patients with relapsed or refractory advanced solid tumors.

- The results demonstrated encouraging signs of anti-tumor activity and the safety profile remained manageable for the two tested dose levels.
- Efficacy assessment of the 21 evaluable patients showed an overall response rate, or ORR, of 33% and a disease control rate, or DCR, of 67% with one complete response, six partial responses and seven patients with stable disease.
- In line with the earlier data presented, particularly encouraging clinical responses were seen in patients with testicular cancer treated with dose level 2 after lymphodepletion (n=7), where one complete response, three partial responses and two stable diseases were observed, representing an ORR of 57% and a DCR of 85%.

We are planning a Phase 2 trial with BNT211 in patients with testicular cancer with a potential 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. Our lead product candidate under this platform is our individualized neoantigen-targeting T-cell therapy, BNT221.

- Concept: Adoptive T-cell therapies targeting personal or shared sets of cancer neoantigens.
• Mechanism: Autologous, neoantigen-specific T cells primed, activated and expanded 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.
• Development Approach: Worldwide rights; wholly owned.

1. BNT221 (NEO-PTC-01) for the Treatment of Cancer

BNT221 (NEO-PTC-01) is our individualized neoantigen-targeting T-cell therapy which targets selected sets of individualized tumor neoantigens.

BNT221 (NEO-PTC-01) Target

BNT221 (NEO-PTC-01) is a personal neoantigen-targeted T-cell therapy candidate derived from patients’ peripheral blood cells. The product consists of multiple CD8+ and CD4+ T-cell populations targeting multiple selected neoantigens from each patient’s tumor.

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; 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 trial evaluating BNT221 (NEO-PTC-01) in patients with checkpoint inhibitor unresponsive or refractory metastatic melanoma is ongoing.

• Part 1 of the trial consists of a monotherapy dose escalation of BNT221 (NEO-PTC-01).
• Part 2, BNT221 (NEO-PTC-01) will be 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 (NEO-PTC-01), as well as evaluations of immunogenicity and preliminary efficacy.

3. Antibody Product Candidates in Oncology

a) Next-Generation Immune Checkpoint Modulators

• Concept: Antibodies for immunomodulation to enhance the immune response against cancer cells, in either monospecific or bispecific format. Monospecific antibodies target a single stimulatory immune checkpoint that is expressed on T cells and NK cells and can enhance immune cell proliferation and activation, whereas bispecific antibodies can either target two immune checkpoints for dual immunomodulation or target an immune checkpoint and a tumor-associated antigen.
• Mechanism: Potent activation of the co-stimulatory immune checkpoint CD27 without the need to crosslink to other targets, or conditional activation of the 4-1BB immune checkpoint only upon simultaneous binding of PD-L1, CD40 (in the case of our initial dual immunomodulation candidates), potentially avoiding toxicities seen in prior attempts at 4-1BB agonism by localizing 4-1BB activation to the tumor microenvironment.
• Development Approach: 50:50 cost and profit share with Genmab, combining our and Genmab’s immunostimulatory antibodies and extensive immunology expertise with Genmab’s proprietary technologies in combination with our joint target identification and product concept expertise. BNT311, BNT312, BNT313 and BNT322 are partnered with Genmab as part of a 50:50 collaboration in which development costs and future profits are shared.
i. BNT311 (GEN1046), a Jointly Owned PD-L1x4-1BB Bispecific Antibody for the Treatment of Solid Tumors

BNT311 (GEN1046), our jointly owned PD-L1x4-1BB product candidate, is a potential first-in-class bispecific antibody combining PD-L1 checkpoint inhibition with 4-1BB checkpoint activation. BNT311 (GEN1046) is currently being evaluated in two clinical trials—a Phase 1/2 trial for the treatment of malignant solid tumors and a randomized Phase 2 trial with BNT311 as monotherapy and in combination with pembrolizumab in patients with recurrent/refractory metastatic NSCLC.

Our BNT311 (GEN1046) Targets

BNT311 (GEN1046) is a PD-L1x4-1BB bispecific antibody that induces activation of T cells through conditional 4-1BB stimulation which is dependent on simultaneous binding to PD-L1. In addition, the PD-L1-specific arm of DuoBody-PD-L1x4-1BB functions as a classical immune checkpoint inhibitor by blocking the PD-1/PD-L1 axis, even in the absence of 4-1BB binding. PD-L1 is a validated target that is expressed on tumor cells. 4-1BB is a trans-membrane receptor belonging to the TNF receptor superfamily and is expressed predominantly on activated T cells. DuoBody is a registered trademark of Genmab.

BNT311 (GEN1046) Trials

Ongoing Phase 2 Trial in metastatic NSCLC

A Phase 2, multicenter, randomized, open-label trial of BNT311 (GEN1046) as monotherapy and in combination with anti-cancer therapy in subjects with relapsed/refractory metastatic NSCLC after treatment with standard of care therapy with an immune checkpoint inhibitor is ongoing.

- This three-arm trial is expected to enroll up to 160 patients with histologically or cytologically confirmed diagnosis of Stage 4 NSCLC with at least 1 prior line of systemic therapy containing an anti-PD-1/PD-L1 monoclonal antibody and that has progressed. Another inclusion criterion is tumor PD-L1 expression of tumor proportion score (TPS) ≥1%.
- The primary endpoint is ORR according to RECIST v1.1.
- Secondary endpoints include DOR, time to response, PFS, OS, and safety.

Ongoing Phase 1/2 Clinical Trial in solid tumors

The ongoing Phase 1/2, open-label, single-arm BNT311 (GEN1046) trial with multiple expansion cohorts, conducted in collaboration with Genmab, is expected to enroll approximately 752 patients with malignant solid tumors.

- The trial consists of a dose escalation part and an expansion part.
- The dose escalation part determines the safety profile of BNT311 (GEN1046) in patients with certain relapsed or refractory, advanced and/or metastatic malignant solid tumors who are no longer candidates for standard therapy.
- The primary endpoints of the trial are dose-limiting toxicities, adverse events and safety laboratory parameters, including hematology, biochemistry, coagulation and endocrinology.
- Dose escalation has been finalized. RP2D has been determined and 11 expansion cohorts are currently ongoing, including patients with NSCLC, TNBC, urothelial cancer, HNSCC and cervical cancer. The expansion phase 2 dose is 100 mg Q3W.

Preliminary clinical data were presented at SITC in 2020 and 2021 showing the safety profile and early single-agent clinical activity.

ii. BNT312 (GEN1042), a Jointly Owned 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) Targets

BNT312 (GEN1042) is a bispecific antibody designed to enhance an anti-tumor immune response by crosslinking CD40 on antigen presenting cells with 4-1BB+ T cells to induce conditional stimulation and co-stimulatory activity in both types of cells. It has demonstrated increased tumor infiltrating lymphocyte expansion in human tumor tissue cultures ex vivo, and induces activation of B cells in the presence of 4-1BB+ cells. Both 4-1BB and CD40 are members of the tumor necrosis factor receptor superfamily.

BNT312 (GEN1042) Trials

Ongoing Phase 1/2 Clinical Trial

A Phase 1/2 dose-escalation trial with expansion cohorts evaluating safety and anti-tumor activity of BNT312 (GEN1042) in patients with solid tumors is ongoing.

- A monotherapy expansion cohort is recruiting patients with advanced or metastatic melanoma after treatment with standard of care.
- BNT312 (GEN1042) is also being explored in combination with other anti-cancer therapies in subjects with advanced or metastatic melanoma, non-small cell lung cancer, head and neck cancer, and pancreatic cancer with no prior systemic therapy.
- Expansion cohorts in melanoma, NSCLC, pancreatic and head and neck carcinoma are actively recruiting.

In 2021, at the SITC Annual Meeting, data from the dose escalation part of the ongoing Phase 1/2 trial of 50 patients who received BNT312 (GEN1042) monotherapy in the dose-escalation part were presented.

- Data demonstrated a favorable safety profile in patients with advanced solid tumors, as well as biologic and early antitumor activity.
- The maximum tolerated dose was not reached, and treatment-related adverse events were mostly mild-to-moderate.
- Increases in peripheral monocyte and dendritic cell cytokines and also increased levels of CD8+ and effector memory T cells were observed, suggesting biological activity that is consistent with the proposed mechanism of action for BNT312 (GEN1042).
- Disease control was achieved in 25 of 50 (50%) patients, including two confirmed partial responses per RECIST1.1 in melanoma and neuroendocrine lung cancer.

In December 2022, at the ESMO Immuno-Oncology Annual Congress, we and Genmab presented a promising preliminary dataset from the safety run-in and expansion cohorts of this Phase 1/2 study investigating BNT312 (GEN1042) combination therapy.

- Data showed that BNT312 + pembrolizumab (PEM) ± chemotherapy (CTx) is well tolerated with no reported DLTs. Most adverse events were grade 1/2 and manageable.
- BNT312 + PEM + CTx showed encouraging early activity in patients with advanced/metastatic HNSCC, with responses observed in 4/4 evaluable patients.
- The observed immune activity mediated by BNT312 (GEN1042) was retained with combination therapy. Enrollment in this trial is ongoing in all cohorts (NSCLC, pancreatic ductal adenocarcinoma, and HNSCC).

iii. BNT313 (GEN1053), a Jointly Owned agonistic CD27 Antibody for the Treatment of Malignant Solid Tumors

In August 2022, we announced the expansion of our global strategic collaboration with Genmab for the joint development of BNT313 (GEN1053). The drug candidate, based on Genmab’s HexaBody technology, is 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.
**BNT313 (GEN1053) Targets**

BNT313 (GEN1053) is a novel CD27 antibody with an IgG Fc domain engineered to induce CD27 agonist activity independently of FcγR-bearing cells.

**Ongoing Phase 1/2 Clinical Trial**

In November 2022, a Phase 1 trial was initiated to evaluate the safety, tolerability, and preliminary efficacy of BNT313 as a monotherapy for the treatment of malignant solid tumors.

- The dose escalation part will explore the safety of escalating doses of BNT313.
- The expansion part is planned to provide additional safety and initial antitumor activity information on the selected dose regimen in selected tumor indications, as well as more detailed data related to the mode of action.

In November 2022, we and Genmab presented preclinical data that characterize the mechanism of action of HexaBody-CD27 at the SITC Annual Meeting.

- In the in vitro experiments, HexaBody-CD27 exhibited CD27 agonist activity independently of Fc gamma receptor-mediated crosslinking. HexaBody-CD27 enhanced activation, proliferation, and proinflammatory cytokine secretion of human CD4+ and CD8+ T cells as well as CD8+ T-cell mediated cytotoxic activity towards tumor cells in vitro.
- In mice expressing human CD27 protein, it enhanced expansion and IFN-γ secretion of antigen-specific CD8+ T cells in vivo. Overall, the data demonstrated a unique potential mechanism of action that distinguishes HexaBody-CD27 from benchmark monoclonal antibodies targeting CD27.

**iv. BNT322 (GEN1056), a Jointly Owned Antibody**

BNT322 (GEN1056) is an antibody product being co-developed with Genmab and for the treatment of solid tumors and for use in combination with other products. The first CTA was submitted for BNT322 (GEN1056) in July 2022. A first-in-human Phase 1 trial of BNT322 (GEN1056) in patients with advanced solid tumors was initiated in November 2022.

**b) Targeted Cancer Antibodies**

i. **BNT321 for the Treatment of Pancreatic Cancer**

In 2019, we acquired certain antibody assets from MabVax Therapeutics Holding, Inc., including BNT321, a clinical-stage targeted cancer antibody. BNT321 is a fully human IgG1 monoclonal antibody targeting sialyl Lewis A (sLea), an epitope on CA19-9 that is expressed in pancreatic and other gastrointestinal cancers that plays a role in tumor adhesion and metastasis formation, and is a marker of an aggressive cancer phenotype.

**Ongoing BNT321 Phase 1 Trial**

BNT321 is being investigated in an open-label, multi-center, non-randomized dose escalation/expansion Phase 1 trial evaluating the safety and recommended Phase 2 dose of BNT321 as monotherapy and combination with mFOLFIRINOX in approximately 108 patients with pancreatic and other CA19-9+ malignancies.

- Secondary objectives include evaluating tumor response rate by RECIST 1.1, duration of response, and determining pharmacokinetics. This study utilizes a conventional 3+3 design to identify the recommended Phase 2 dose.

4. Oncology Small Molecule Immunomodulator Product Candidates

- Concept: Small molecule therapies, with a specific focus on TLRs, that can be used synergistically with other cancer therapeutics, including other product candidates in our portfolio.
- Development Approach: Worldwide rights; wholly owned.

i. **BNT411, a Small Molecule TLR7 Agonist for the Treatment of Solid Tumors, Including Small Cell Lung Cancer**

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 NK cells and macrophages.

104
Ongoing Phase 1/2 Trial

A phase 1/2, first-in-human, open-label, dose-escalation trial with expansion cohorts evaluating safety, PK, PD, and preliminary efficacy of BNT411 as a monotherapy in patients with solid tumors and in combination with atezolizumab, carboplatin and etoposide in patients with chemotherapy-naive ES-SCLC is ongoing.

In 2021, at the SITC Annual Meeting, preliminary data from the monotherapy arm of the dose escalation part was presented, demonstrating an acceptable safety profile at all doses tested as a monotherapy and in combination with atezolizumab, carboplatin and etoposide.

B. Infectious Disease Programs

Infectious diseases remain among the leading causes of death and disability worldwide: in 2019, 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, including TB, 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 and pipeline while democratizing access to mRNA medicines.

1. Next-generation COVID-19 vaccine – BNT162b5 and BNT162b2 + BNT162b4

In July 2022, we and Pfizer initiated a randomized, active controlled, observer-blind Phase 2 study to evaluate the safety, tolerability and immunogenicity of a 30-µg dose of an enhanced spike antigen vaccine candidate, BNT162b5. This is the first of multiple vaccine candidates with an engineered design, aimed to increase the magnitude and breadth of antibody neutralization response to better protect against COVID-19.

In November 2022, we and Pfizer initiated a Phase 1 study to evaluate the safety, tolerability and immunogenicity of a next-generation COVID-19 vaccine component, BNT162b4, dosed in combination with the Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine, that aims to enhance and broaden SARS-CoV-2 T-cell responses.

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

In October 2022, we and Pfizer initiated a Phase 1 open-label, dose-finding study 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 have received Fast Track Designation from the U.S. FDA for the mRNA-based combination vaccine candidate for influenza and COVID-19.

3. Influenza Vaccine Program – BNT161

In 2018, we and Pfizer agreed to collaborate on an mRNA program in influenza. The collaboration was established to develop an influenza vaccine based on our suite of mRNA platforms to better address the burden of influenza and further reduce the yearly rates of the severe outcomes, including hospitalization and death. WHO estimates that influenza is responsible for 290,000 to 650,000 deaths annually on a global scale (WHO 2023). The research collaboration period ended in August 2021, and Pfizer now has the sole responsibility, authority and control of the development, manufacturing and commercialization of all candidates and products.

In July 2022, Pfizer reported data from the Phase 2 clinical trial of BNT161 in subjects 65 years of age and older showing first evidence of substantial induction of strain specific CD4+ and CD8+ T-cell responses.

• At day seven after vaccination with BNT161, the geometric mean fold rise, or GMFR, for CD4+ T cells was more than two-fold for all four encoded strains. For strain specific CD8+ T cells the GMFR was more than two-fold for the influenza B Victoria-lineage strain and influenza A H3N2 subtype. The GMFR was higher compared to the control quadrivalent influenza vaccine for both CD4+ and CD8+ strain specific T-cell responses.
In September 2022, Pfizer initiated a Phase 3 clinical trial to evaluate the efficacy, safety, tolerability and immunogenicity of a quadrivalent modified RNA (modRNA) influenza vaccine candidate in approximately 36,000 healthy U.S. adults.

4. HSV-2 Vaccine Program – BNT163

BNT163 encodes three HSV-2 glycoproteins with the aim of helping to prevent HSV cellular entry and spread, as well as counteract immune evasion properties of HSVs. An estimated 491 million people aged 15 - 49 worldwide have an HSV-2 infection (2016 data, WHO 2022) with painful genital lesions, an increased risk for meningitis and high levels of emotional distress. Once acquired, HSV persists lifelong in the body with recurring symptomatic outbreaks. Moreover, HSV-2 infection increases the risk of acquiring HIV infections by approximately three-fold, and co-infections with both HIV and HSV-2 increase the likelihood of transmitting HIV to others, according to the National Institutes of Health. No vaccine has been approved for prevention of genital lesions caused by HSV to date. Currently available HSV therapies only reduce the severity and frequency of symptoms.

In December 2022, we dosed the first subject in a first-in-human Phase 1 clinical trial 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.

5. Tuberculosis Vaccine Program – BNT164

We have collaborated with the Bill and Melinda Gates Foundation since 2019 to develop vaccine candidates aimed at preventing tuberculosis infection and disease. Tuberculosis is a worldwide leading cause of death due to an infectious disease, second only to COVID-19. In 2021, approximately 10.6 million people developed active tuberculosis and 1.6 million people died from this disease. The WHO estimates that 25% of the world's population is latently infected with Mycobacterium tuberculosis, the bacteria responsible for the disease, and approximately 5 to 10% of infected individuals will develop tuberculosis disease.

A clinical trial for the tuberculosis vaccine candidate, BNT164, is planned to begin in 2023.

6. Malaria Vaccine Program – BNT165

BNT165b1 encodes certain parts of the circumsporozoite protein (CSP). The WHO estimated that there were 247 million cases of malaria and 619,000 associated deaths in 2021 (WHO 2022). *P. falciparum* caused the majority of deaths in sub-Saharan Africa. Sub-Saharan Africa (SSA) carries the heaviest malaria burden, with an estimated 234 million cases (95%) and 593,000 deaths (96%) in 2021. Children under 5 years old represent the most vulnerable population, due to a high risk of severe disease progression and chronic complications.

Announced in July 2021, our Malaria project aims to develop a well-tolerated and highly effective mRNA vaccine with durable immunity to prevent blood-stage malaria infection, thereby reducing morbidity and mortality as well as onward transmission, and to develop sustainable vaccine production and supply solutions on the African continent.

In December 2022, we initiated a first-in-human study with BNT165b1, the first candidate from our BNT165 program, to develop a multi-antigen malaria vaccine candidate. We will initially evaluate a set of mRNA-encoded antigens of the malaria-causing parasite *Plasmodium falciparum* (*P. falciparum*) to help select the multi-antigen vaccine candidate to proceed to planned later-stage trials. This first clinical trial (NCT05581641) will evaluate the safety, tolerability and exploratory immunogenicity of the vaccine candidate BNT165b1.

7. Shingles Vaccine Program – BNT167

Shingles is a debilitating, disfiguring, and painful disease, and is the chronic form of the varicella zoster virus (VZV), which causes an initial chickenpox infection. The virus can lay dormant in human nerve cells and can re-activate later in life due to stress or immunocompromise, potentially leading to postherpetic neuralgia and in rare cases, facial paralysis, deafness, and blindness. Globally, about 95% of individuals older than 50 years of age have been exposed to VZV, placing them at risk of developing shingles. While there are currently approved vaccines for shingles, there is an opportunity to develop an improved mRNA vaccine that potentially shows high efficacy and better tolerability and is more efficient to produce globally.
In January 2022, we and Pfizer announced a global agreement to develop the first mRNA-based shingles vaccine candidate. Under the terms of the agreement, the companies will leverage a proprietary antigen technology identified by Pfizer’s scientists and our proprietary mRNA platform technology used in the companies’ COVID-19 vaccine.

In February 2023, we and Pfizer began a Phase 1/2 clinical trial exploring the safety, tolerability, and immunogenicity of BNT167 in up to 900 healthy volunteers 50 to 69 years of age. The Phase 1 clinical trial will help select the optimal mRNA vaccine candidate, dose level, dosing schedule, and formulation for advancement to Phase 2 testing.

8. 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. The 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.

9. Research Collaboration with University of Pennsylvania

A new collaboration and license agreement was signed with the University of Pennsylvania in January 2023. The agreement is in addition to the existing 2018 collaboration and license agreement between the parties. The agreement includes early research programs to help develop mRNA-based diagnostics, therapeutics, and delivery technologies. We will provide funding support and the University of Pennsylvania will be responsible for research and development up to the completion of an IND-ready data package. We have an option to license technologies under the agreement.

V. Scientific Background: mRNA Technology

At a glance: mRNA as a Therapeutic Drug Class

- Natural molecule found universally within cells, with well-characterized properties.
- Suitable to encode for antibodies, antigens, cytokines and any other type of protein.
- Transient, with adaptable activity and half-life. Avoids genomic integration problems sometimes seen in gene therapy, potentially resulting in a better safety profile.
- Can be designed and optimized pharmacologically and immunologically, making it suitable for a broad range of applications.
- Fast manufacturability, making it a cost-effective and flexible therapeutic to produce.
- Our mRNA portfolio includes BNT162b2, our mRNA-based COVID-19 vaccine, which has received emergency or temporary use authorization or approval or has been granted conditional marketing approval in over 100 countries.

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. All mRNA is assembled from ribonucleotide residues; individual mRNA products differ from one another in the identity and sequence order of such residues, allowing them to encode a variety of different proteins. Established mRNA manufacturing technologies can be quickly adapted to produce mRNAs of different sequences, permitting rapid development of mRNAs with potential to treat 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 a desired therapeutic protein. Based on the information encoded by the mRNA, 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 from a DNA template. With the exception of the 5’ cap, the template determines all structural elements of the mRNA. 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 it from breakdown by extracellular RNAses. 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. Secreted 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.

General principles of mRNA pharmacology. Step 1: mRNA is formulated as nano-particles to protect degradation by extracellular enzymes and is taken up by cells. Step 2: Subsequently, mRNA is released from endosomes into the cytoplasm. Step 3: mRNA is translated by the protein synthesis machinery of host cells. Step 4: Termination of translation by degradation of mRNA. Step 5: The translated protein product acts in the cell in which it has been generated. Step 6: Alternatively, the protein product is secreted and may act via autocrine, paracrine or systemic, body-wide mechanisms. Steps 7 and 8: For vaccine activity, mRNA encoded antigens are degraded into shorter fragments and loaded onto MHC class I and class II molecules. Step 9: Protein-derived epitopes can then be presented on the cell surface by both MHC class I and MHC class II molecules, enabling stimulation of CD8+ and CD4+ T cells.

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

Our mRNAs all contain basic structural elements, including the 5' cap, the untranslated regions and the poly(A) tail, in addition to a coding sequence, that are encoded by our DNA template.

- 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. This particular cap analogue is extremely useful for our immunotherapy approaches.

- 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 removing contaminating double-stranded RNA 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. We believe these fine tunings of the respective molecules provide great benefit to the purpose-adapted performance of our mRNA.

Our mRNA formats. As shown above, we have developed four mRNA formats, each optimized for different therapeutic applications. Abbreviations: y, 1-methyl/pseudouridine; UTR, untranslated region.

Our mRNA formats include:

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 (augmented antigen 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 production of anti-drug antibodies and 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 replication, while not being an infectious, disease-causing agent itself. saRNA resembles conventional mRNA encoding the protein of interest, but also encoding a polymerase, called replicase, that multiplies part of the mRNA within the target cell. During self-amplification inside the cell, a double-stranded RNA intermediate is generated, which is recognized by intracellular immune sensors. This makes saRNA a very potent activator of the immune system and therefore an excellent category of immunotherapy. 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 application in infectious diseases with high medical needs.

4. Trans-amplifying mRNA (taRNA)

We have also expanded on our self-amplifying mRNA capabilities, developing a novel mRNA amplification technology by separating the target mRNA to be amplified and the replicase encoding mRNA. This advancement broadens the spectrum of applications by making the development of therapeutic 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 is particularly well-suited for prophylactic vaccines to prevent infectious diseases.

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.

We employ multiple mRNA delivery formulations, each designed for different functions and optimized for therapeutic product needs:

- **Lipoplex**: Our lipoplex formulation, or LPX, embeds the mRNA between a lipid bilayer, which is used for our FixVac and iNeST platforms. We use a proprietary size- and charge-based non-viral mRNA lipoplex that was developed to deliver mRNA to dendritic cells in lymphoid compartments such as the spleen for optimal antigen presentation and immune response activation.

- **LNPs**: For other applications, we encapsulate our mRNA in lipid nanoparticles, or LNPs. These formulations are suitable for our RiboMab, RiboCytokine, and rare disease protein replacement platforms. Our LNP formulations can be adjusted according to our needs for delivery to particular target tissues, such as the liver in the case of our rare disease protein replacement platform.

- **Polyplexes**: Our portfolio also comprises polyplexes, which are being utilized in certain of our discovery programs, in which the mRNA is bound to a polymer and then forms nanoparticles.

**RNA-LPX Technology**

At a glance: RNA-LPX Cancer Immunotherapy Technology

- Potential first-in-class clinical intravenous nano-particulate mRNA immunotherapy, allowing systemic delivery.
- Strong potency by systemic targeting to dendritic cells in lymphoid tissues.
- Universally applicable for all cancer antigens.
- Opportunity to deliver multiple antigens in parallel, enabling the induction of poly-specific T-cell responses.
- Synchronized adjuvant effect mediated by TLR7-triggering and type-I interferon-driven innate and adaptive immune stimulation.
- Preclinical anti-tumoral activity demonstrated against multiple tumors.
To advance from local to systemic dendritic cell, or DC, targeting, we developed an innovative liposome-based RNA-lipoplex formulation, RNA-LPX, that allows for intravenous administration of our mRNA cancer immunotherapies. We have demonstrated in the clinic that systemic DC targeting by mRNA cancer immunotherapies can result in potent activity at very low doses. Consequently, less material is required for treating high patient numbers, making manufacturing more cost-effective.

Our RNA-LPX technology. Our proprietary RNA-LPX formulation is designed to deliver vaccine mRNA precisely into DCs and macrophages in the spleen and other lymphoid compartments. The RNA-LPX has an inherent adjuvant function stimulating the release of cytokines such as IFN-α thereby promoting the activation of DCs and the induction of strong T-cell responses. Abbreviations: BM, bone marrow; LN, lymph node; DC, dendritic cell; pDC, plasmacytoid dendritic cell; Mø, macrophage; IFN-α, interferon alpha.

RNA-LPX protects mRNA from degradation outside of the cell and mediates its efficient uptake and expression of encoded antigens in various dendritic cell populations. Our RNA-LPX technology is designed to target a wide variety of antigens and address cancer patients with all possible HLA haplotypes. Utilizing RNA-LPX, we can target fixed groups of known shared antigens with our FixVac platform and a whole new class of patient-specific neoantigen targets with our iNeST platform.

RNA-Lipid Nanoparticle Formulation for infectious disease vaccines

Our COVID-19 Vaccine BNT162b2 is based on an RNA-LNP platform of nucleoside modified RNA, which has blunted innate immune sensor activating capacity and thus augmented antigen expression. BNT162b2 encodes a P2 mutant S (P2 S) and is 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 mixing of the RNA and the dissolved lipids, the lipids form the 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.
D. mRNA Platforms

We are developing multiple mRNA-based therapeutic platforms. These include FixVac, iNeST, mRNA-based intratumoral immunotherapy, RiboMabs, and RiboCytokines in the oncology space. In addition, we have implemented mRNA platforms for the development of infectious disease vaccines and protein replacement therapies for rare diseases.

Importantly, each of these platforms enables the development of multiple pharmaceutical product candidates or programs.

Our mRNA Platforms. We have multiple mRNA-based platforms utilizing different mRNA formats and delivery formulations, directed at a range of biological targets in oncology and infectious and rare diseases.

VI. Sales, Marketing and Distribution

Our commercial organization focuses on supporting sales of our COVID-19 vaccine in Germany. Our commercial organization is responsible for promoting our products to health care providers and providing information to stakeholders, including governmental organizations, in Germany and Turkey. Our commercial organization is also responsible for preparing and obtaining reimbursement from third-party payors, including governmental organizations, for our COVID-19 vaccine and will have the same responsibilities for our clinical-stage oncology product candidates, if approved.

VII. Manufacturing

We are building a fully integrated biotechnology company, with operations spanning from research through clinical development, and manufacturing through sales and marketing. To successfully bring individualized immunotherapies to patients and vaccines to people around the world, it is crucial to have in-house manufacturing capabilities that can be scaled for global clinical and commercial distribution. We have several manufacturing sites capable of developing automated production processes for on-demand production of our 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 for our own pipeline and for external customers, including a state-of-the-art, multi-platform, GMP-certified manufacturing facility located in a lift science industrial park in Marburg, Germany, which we acquired in October 2020 from Novartis AG 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 internal research and development, as well as from our collaborators. We have done so by continuing to make significant investments in manufacturing infrastructure and increasingly expanding our capacity to manufacture mRNA, viral vectors, cellular
products and peptides. We believe the development and optimization of our manufacturing processes in parallel to drug development is crucial to our success. We have also collaborated with Siemens to develop a process for an automated, on-demand production of mRNA therapies.

A. Manufacturing Operations

COVID-19 Vaccine. Our manufacturing site in Marburg was approved by the EMA for manufacturing of the COVID-19 drug product in March 2021. This approval makes it one of the largest mRNA manufacturing sites worldwide alongside two of our existing GMP facilities, which currently produce the COVID-19 vaccine candidates for clinical trials. Marburg reached an annual capacity of more than 1 billion doses mRNA drug substance in 2021. The first vaccines manufactured at the Marburg site were delivered in April 2021. 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, not 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 7000 vials at IMFS. Batch sizes range from a few milligrams for individualized applications (i.e., iNeST) to 10 g for standard mRNA applications (i.e., FixVac, intratumoral immunotherapies and infectious diseases), and up to 360 g batches for COVID-19. In 2022, we further increased the mRNA batch size at our facility in Marburg. Our manufacturing facility in Marburg is one of the largest mRNA vaccine manufacturing sites worldwide with an annual capacity of up to 3 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 2000 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 currently have the capacity to meet the supply needs of our product candidates in clinical trials up to registration.

In recent years, we have successfully decreased the time required to deliver individualized immunotherapy (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 have already demonstrated 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 over 20 years of experience in cell therapy manufacturing. Our manufacturing process for cellular products involves the isolation of primary human cells and subpopulations, including CD34+ and CD3+ cells. We engage in the culture, expansion, and genetic modification of primary human cells as well as mammalian cell lines. Our processes include vector production for transfection of cells with CARs, cell banking and cryopreservation.

We have set up a broad range of quality control assays for the characterization of cell therapy products that allow us to certify the manufactured drug products in a short time. We are a leader in the production of gamma retroviral vectors. To date, we have produced more than 50 different cell therapy products.

Peptides. Our custom peptide synthesis business has developed unique technologies to produce several million peptides during the past three 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 plan to establish a new production facility, which will roughly double our current capacity.
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 8 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. In 2022, we installed a capacity to produce up to 3 billion doses of mRNA Drug Substance vaccine.

Marburg is our central hub for innovation and development of novel manufacturing solutions and approximately 62 million euros have been invested since acquisition. Finally, Marburg 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 the new manufacturing facility to enable 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 InNeST 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. More than 500 staff members are employed at this facility, with collective expertise in molecular biology, cell biology and virology. BioNTech IMFS is our powerhouse for early stage mRNA material and is working closely with our R&D teams in Mainz.

Mainz

BioNTech InNeST Clinical Manufacturing (East Wing): We dedicate our GMP-certified manufacturing facility at our headquarters in Mainz, Germany to the production of InNeST 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 InNeST 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 4,500 square feet of GMP facilities. About 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, since inception, manufactured and released more than 1,200 batches of mRNA.

To perform our upstream process to feed into the InNeST downstream GMP manufacturing process, the 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 10,000 square feet of clean rooms, laboratory and office space.

**Global Manufacturing Sites**

Outside of Europe, we have acquired a site in the U.S. for the clinical-scale manufacture of cell therapies and a site in Singapore for the manufacturing of clinical- and commercial-scale mRNA therapies. Recently, we announced our modular mRNA facility, the BioNTainer, with multiple governments around the world, with Rwanda as our first location.

**Gaithersburg Clinical Manufacturing Facility**

In August 2021 we acquired a site in Gaithersburg, Maryland from Kite Pharma, Inc. The focus of the Gaithersburg site is to supply cell therapy products for clinical trials in the U.S. 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 a great example of our innovative approach to globalized delivery. 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 drug formulation module. Each module is built of six ISO-sized containers. The BioNTainer will 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. 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. This solution is an important step to improve global vaccine supply. In December 2022, the six ISO-sized shipping containers for the first BioNTainer finished construction in Europe and underwent quality checks by our experts. They arrived in Kigali, Rwanda in March 2023. We also aim to build BioNTainers for other partner countries Australia, Senegal, and Israel to meet their specific needs.
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.

VIII. 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:

- Pfizer for our COVID-19, influenza and joint COVID-19/influenza vaccine programs, which leverage technology from our infectious disease mRNA-based platform;
- Fosun Pharma for our COVID-19 vaccine program;
- Genentech for our iNeST platform in our mRNA drug class; and
- Genmab for our next-generation checkpoint immunomodulator platform in our antibodies drug class.

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. Pfizer COVID-19 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 U.S. 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 Turkey (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 Turkey, 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 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 mRNA 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.

B. Fosun COVID-19 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.

118
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.

C. 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 to 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 Product, 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 U.S. 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.

120
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 IMS.

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 U.S. 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).

**D. 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.

121
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.

E. 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 U.S. 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.

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 of a product 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.

IX. Government Regulation

Government authorities in the U.S. 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 U.S. and in foreign countries and 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 U.S.

In the U.S., 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 U.S. 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 U.S. 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 the FDA is able to validate the study data through an onsite inspection, if necessary.

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.

1. 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 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 drug is safe, pure and potent and the facility where the drug 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 within 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 patient 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 biological 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).

128
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 a meaningful 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 the product 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 xenogenic 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 unscheduled 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 U.S. is designed to encourage sponsors to develop products intended for rare diseases or conditions. In the U.S., a rare disease or condition is statutorily defined as a disease or condition that affects fewer than 200,000 individuals in the U.S. or that affects more than 200,000 individuals in the U.S. 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 U.S.

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 U.S. 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 U.S. 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 replaces the current Clinical Trials Directive 2001/20/EC. Commission Implementing Regulation (EU) 2017/556 replaces the GCP Directive 2005/28/EC. The Regulation overhauls the current 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, from January 31, 2023, clinical trial sponsors need to use CTIS to apply to start a new clinical trial in the EU/EEA and such trials must be run under the Regulation.

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 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 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, the EMA 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 U.S. 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 cells 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.

**Human Cells and Tissues**

**Human Cells and Tissues**

**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 U.S. 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 U.S. (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 U.S., 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 rates 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 for a product 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 federal, state and foreign 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 U.S., 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. Brexit and the Regulatory Framework in the 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. In 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 reliance route will be available to companies until December 31, 2023 and there are new proposals for reliance routes recognizing EU, U.S. and certain other country regulatory approvals going forward.

Currently, domestic United Kingdom law provides that all existing European Union law in force on December 31, 2020 is retained in UK national law, subject to certain revisions that have become necessary as a result of Brexit. Thus, at least initially, the United Kingdom and the European Union laws are aligned. However, the UK Government has introduced the Retained EU Law (Revocation and Reform) Bill into Parliament, which proposes that all retained European Union law will expire on December 31, 2023 (or at the latest June 23, 2026). The Bill proposes to grant certain powers to Government Ministers to make regulations in affected areas.

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, including the Windsor Framework Political Declaration.

E. Greater China

a) Mainland China

Similar to the U.S. 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. 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 vaccine good clinical practice regulations and related guidelines. Furthermore, prior to the commencement of the clinical trial in China each site’s ethics committees must approve the trial, and the Office of Human Genetic Resources Administration must approve the use of samples and related 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. Once approved, the HGR approval/filing may require updates and amendments and additional procedures to transfer data to certain foreign parties. 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 vaccine. 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 “special approval” procedures for drugs needed to control a public health emergency and/or conditional approval procedures. 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 good manufacturing practice inspection. Preclinical studies and initial clinical trials can still be conducted in China subject continued marketing to the fulfillment of post-market conditions with a designation period of time, such as the completion of additional studies.

At both the clinical trial and MA stages, drug applicants located outside of China 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
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, safety and annual quality reporting and compensation for injuries caused adverse events following inoculation, or AEFIs. MAHs of vaccines that are not part of the National Inoculation Program, or NIP, must bear the cost of injuries determined by experts to be AEFI injuries. The government bears the cost of NIP vaccines and related AEFIs. Vaccine MAHs are also subject to other post-market obligations for drug marketing authorization holders, including recalls, annual reporting, and inspections. Vaccine MAs must typically be renewed every five years, and supplemental applications, notifications, or reports may need to be submitted for minor, moderate and major changes 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 registered 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.

b) Hong Kong and Macao

Mainland China’s drug regulatory system does not apply in Hong Kong or Macau. These administrative regions are governed by separate laws on the development and approval of drugs, including vaccines. They also have separate laws on the importation and distribution of those vaccines.

F. Turkey

Other countries such as Turkey 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 market authorization requirements, manufacturing/testing facility inspections, testing of drug product upon importation and other domestic requirements. Some countries, such as Turkey, 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 EU and the U.S. 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 US and the EU is similarly governed by vaccine supply agreements with local governments.

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 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 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 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 clearingshouses and their respective business associates;

• the 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;

• federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

• 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 state and foreign laws and regulations, such as 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 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. State and foreign laws 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. 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 U.S. and foreign 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. 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.

Additionally, other federal health reform measures have been proposed and adopted in the U.S. 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 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 manufacturers patient programs, and reform government program reimbursement methodologies for products. In addition, the federal government, state legislatures and foreign 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 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 U.S. 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 U.S.

If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. 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 U.S. Environmental, Health and Safety Laws and Regulations

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.

X. Intellectual Property

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 for examination by the USPTO and its foreign equivalents 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 U.S. and various foreign 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 US 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 foreign patent filings directed to lipid nanoparticles and polyplex technologies, which are solely owned by BioNTech or jointly owned by BioNTech and TRON. 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. 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 foreign 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) is our most advanced mRNA product, and is sold in monovalent (based on the Original strain; marketed as Comirnaty) and bivalent (one RNA based on the Original strain and one RNA based on an Omicron variant) formats. The monovalent format has received full U.S. FDA approval for individuals 12 and older and emergency use authorization 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 Emergency Use Authorization (EUA) by the FDA in the U.S. 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 conditional 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. 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.

Comirnaty and Other COVID-19 Vaccine mRNA Product Candidates

Both our marketed monovalent and bivalent COVID-19 vaccines utilize nucleoside-modified mRNA formulated in lipid nanoparticles and encoding 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, and interrupted polyA tails), including filings which 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 BNT162b2 structure (including so may be tailored based on particular SARS-CoV-2 variants), composition, formulation, packaging, use and/or manufacture, or 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 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 RNAs containing modified nucleosides, including as used in BNT162b2. We also have a non-exclusive license from the National Institutes of Health granting us right to use certain US and European patent filings that may relate to SARS-CoV-2 spike (S) protein variants 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, grants 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 composition, formulation, packaging, use and 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 proteins that are highly conserved across a broad range of SARS-CoV-2 variants and were chosen based on our proprietary target prioritization platform and is being assessed in combination with our bivalent COVID-19 vaccine product, and BNT162b5, 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**

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 EASi.

**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 BNT162b2 Platform Filings, include certain 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-2030s 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 foreign 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 foreign 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, a related EP patent number 3473267 from the same patent family with claims reciting steps relating to neoantigen selection for an RNA vaccine encoding a recombinant polypolypeptide is 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) have/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 Sublicences, 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.

147
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 Acutans and Genevant 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 Penn to develop infectious disease mRNA vaccines, some of which are currently in clinical trials at different phases, including as mRNA vaccines against influenza (Phase 3) and HSV 2 (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.

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 and/or that may be of interest to our collaborators, 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 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 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. Our COVID-19 vaccine product (Comirnaty) has been approved and our bivalent version (Original and Omicron BA.1/BA.5) has been authorized under Emergency Use Authorization (EUA) by the FDA in the U.S. for individuals 12 and older. In addition, both Comirnaty and our bivalent vaccine were also authorized by the FDA in the U.S. under EUA for individuals 6 months to <12 years old. As different 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, 2023, our overall owned and in-licensed patent portfolio included more than 300 patent families, each of which includes at least one filing in the U.S. or Europe, and several of which are pending or granted in multiple jurisdictions. The patent families include at least 100 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, selling or offering to sell or importing our products, in the jurisdiction in which the patent is issued. In the U.S., 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 U.S., require the payment of periodic maintenance fees in order for patents to remain in force for the full 20-year term. The U.S. 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 U.S. and certain other jurisdictions also have provisions that permit extension of patent term for patent claims priority). However, many jurisdictions, including the U.S., require the payment of periodic maintenance fees in order for patents to remain in force for the full 20-year term. The U.S. 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 U.S. 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 U.S., 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. We did not extend any patent for our COVID-19 vaccine (Comirnaty) when it was approved by the FDA in the U.S. in 2021. The U.S. 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.
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 U.S. 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 or CD-40. 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 imidaaziquinolines, 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. We have entered into material intellectual property licensing or option arrangements with TRON, Louisiana State University and MRT-CellScript.

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, Eulfts GmbH and JPT Peptide Technologies GmbH entered into a Master Agreement for Research Services with TRON. Concurrently with this Master Agreement for Research Services, we entered into a License Agreement with Ganymed, TRON, Johannes Gutenberg-Universität Mainz and Universitätmedizin 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 Development 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 develop, 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 U.S., 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 Sublicences discussed above. Together, the MRT-CellScript Sublicences grant BioNTech RNA worldwide, non-exclusive sublicenses under the Penn Modified mRNA Patent Rights (as defined in the MRT-CellScript Sublicences) 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 sublicences, BioNTech RNA has the right to grant sublicences to affiliates and third parties.

BioNTech RNA must use reasonable efforts to develop and commercialize products under the sublicences. 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, Ribovyskine, Ribomab, Recon, Neo-Stim, Precision Neo-Stim, and Maptac, 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.

XI. 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.

155
Specifically, our marketed monovalent and bivalent COVID-19 vaccines and any other COVID-19 vaccines we and Pfizer develop would 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.

XII. Legal Proceedings

Claims mainly related to purported obligations arising out of certain contractual disputes unrelated to the below mentioned patent proceedings had previously been reflected as provisions in our consolidated statements of financial position (as of September 30, 2022 our provisions for legal proceedings amounted to €359.1 million). In our consolidated financial statements as of and for the year ended December 31, 2022 our provisions for legal proceedings were mainly released due to the favorable outcome of such proceedings received in March 2023 and treated as an adjusting event.

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, 2022, 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 relfance thereon, scientific evidence and findings, actual and provable injury, and other matters. These complexities vary from matter to matter. As of December 31, 2022, 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, 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 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

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 DE202015005751U1. Later 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 August 2022, CureVac added European Patent EP370866B1, or the EP’668 Patent, to its German lawsuit. 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 addition, we filed a nullity action in the Federal Patent Court of Germany seeking a declaration that the EP’122 Patent is invalid. Lastly, on November 11, 2022, we filed cancellation actions seeking the cancellation of the three German Utility Models in the German Patent and Trademark Office. All of the 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 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.

Moderna Proceedings


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.
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 (approximately 101,353 square feet) of laboratory, GMP manufacturing, storage and office space at An der Goldgrube 12, 55131 Mainz. We acquired ownership of the building in December 2022.
  • Approximately 8,446 square meters (approximately 90,912 square feet) of office and laboratory container space at Freiligrathstr. 6, 55131 Mainz. The lease of the office container space expires on June 30, 2027. The laboratory container space is owned by us.
  • Approximately 1,049 square meters (approximately 11,291 square feet) of office and GMP manufacturing space under a lease for part of the building located at Kupferbergterrasse 15, 55161 Mainz under a lease that expires on March 31, 2027.
  • Approximately 4,882 square meters (approximately 52,549 square feet) of laboratory and office space located at Adam-Opel-Straße 10, 55129 Mainz, which is owned by us, as well as 9,278 square meters (approximately 99,868 square feet) 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 (approximately 22,873 square feet) office container space.
  • We also own a plot of land of approximately 8,753 square meters (approximately 94,216 square feet) at Hechtsheimer Straße 2, 55131 Mainz, where construction for a GMP manufacturing facility of approximately 18,000 square meters (approximately 193,750 square feet) has commenced in 2021.
  • Approximately 42,164 square meters (approximately 453,850 square feet) of office space under a lease for two of three building parts at Große Börse 54-56, 55131 Mainz under a lease that expires on December 31, 2029.

In Idar-Oberstein:
• The IMFS facility consists of approximately 2,800 square meters (approximately 30,140 square feet), which includes 650 square meters (approximately 7,000 square feet) of clean room area, and 700 square meters (approximately 7,500 square feet) of development and quality control laboratories.
  • We occupy approximately 575 square meters (equivalent to approximately 6,200 square feet) 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.
  • We occupy approximately 100 square meters (equivalent to approximately 1,075 square feet) of this space, which is used primarily for storage, under a lease that can be terminated by either party on six months’ written notice (but not earlier than May 1, 2020).
  • We occupy approximately 80 square meters (equivalent to approximately 860 square feet) of this space, which is used as office space, under a lease that can be terminated by either party on three months’ written notice.
  • The rest of this facility, including the GMP-certified manufacturing suites, is owned by BioNTech.
• In 2022, we completed construction of two new buildings at the IMFS facility, and now occupy an additional 780 square meters (approximately 8,395 square feet) of clean room space and 550 square meters (approximately 5,900 square feet) of laboratory space, expanding our capacity for GMP cell therapy manufacturing, and 650 square meters (approximately 7,000 square feet) of office space.
• We have added 2,106 square meters of container space for QA and QC processes (approximately 22,669 square feet) at Vollmersbachstraße under a lease which expires on July 31, 2025.

In Marburg:
• Our manufacturing facility consists of approximately 10,240 square meters (approximately 110,220 square feet), including 4,589 square meters (approximately 49,400 square feet) of GMP space, 2,422 square meters (approximately 26,070 square feet) of technical and storage facilities, 540 square meters (approximately 5,810 square feet) of laboratory space and 2,690 square meters (approximately 28,960 square feet) of offices. The lease will expire December 31, 2034.
• We also occupy approximately 2,040 square meters (approximately 21,958 square feet) of GMP and office space under a lease which will expire April 30, 2032.
• We are also currently expanding into a new facility of 2,882 square meters (approximately 31,022 square feet) under a lease which is due to expire November 30, 2023.

In Berlin:
• At our JPT facility, we occupy approximately 1,794 square meters (approximately 19,299 square feet) of office, laboratory and other space:
  • Approximately 250 square meters of that space (approximately 2,690 square feet) is occupied under a lease which had an expiry date of June 20, 2020 but continues for further six-month periods, unless terminated by either party on three months’ prior written notice.
  • Approximately 1,523 square meters (approximately 16,199 square feet) are occupied under a lease for an indeterminate period but which may be terminated by either party on 12 months’ prior written notice.
  • The remaining approximately 20 square meters (approximately 215 square feet) of storage space is occupied under a lease on a monthly basis and can be terminated by either party giving two weeks’ written notice.
• A new laboratory and office building at Adlershof, which is owned by JPT, is currently under construction.

In Martinsried, we occupy approximately 1,862 square meters (approximately 20,042 square feet) under a lease which will expire on December 31, 2026.

In Neuried:
• We occupy approximately 1,732 square meters (approximately 18,643 square feet) 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 (approximately 15,822 square feet) of laboratory, office and storage space under a lease which will expire on August 30, 2029.

In Fussgoenheim, we occupy approximately 3,869 square meters (approximately 41,645 square feet) of freezer farm space under a lease that has an initial term that expires on December 31, 2023 and will renew automatically for an additional one-year period until terminated.

In Mutterstadt, we occupy approximately 5,269 square meters (approximately 56,715 square feet) of freezer farm space under a lease that has an initial term that expires on December 31, 2023 and will renew automatically for an additional one-year period until terminated.

We intend to expand our capacity as follows:
• In January 2022, we commenced construction of a four-story building at An der Goldgrube 12 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 occupy an additional 24,000 square meters (approximately 258,300 square feet) of laboratory space and office space.
On January 13, 2022, we purchased property for the construction of a new office building adjacent to the planned iNeST GMP manufacturing facility. Upon completion of the construction project, we will occupy up to approximately 6,100 additional square meters (approximately 65,650 square feet) of usable floor space for offices, storage, meeting areas and cafeteria.

Global locations:

In Cambridge, Massachusetts, we principally occupy:
- Approximately 2,490 square meters (approximately 26,802 square feet) 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, but which we have the option to extend until September 30, 2029.
- Approximately 1,672 square meters (approximately 18,000 square feet) of laboratory and office space for part of a building located at 45-75 Sidney Street under a lease which will expire on December 31, 2024.

In Gaithersburg, Maryland, we are leasing approximately 5,476 square meters (approximately 60,022 square feet) under a lease which will expire on July 31, 2033.

In Vienna, Austria, we signed a lease in September 2022 for approximately 1,300 square meters (approximately 14,000 square feet) of office and laboratory space for part of the building located at Helmut-Qualtinger-Gasse 2, 1030 Vienna, Austria. The lease commencement date is 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 (approximately 377,800 square feet) to develop an mRNA vaccine factory for the manufacturing of bulk drug substance and bulk drug product.

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:

<table>
<thead>
<tr>
<th>Revenues</th>
<th>€ (in millions)</th>
<th>2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial revenues</td>
<td>€17,194.6</td>
<td>€18,874.0</td>
<td>€303.5</td>
<td></td>
</tr>
<tr>
<td>Research &amp; development revenues</td>
<td>116.0</td>
<td>102.7</td>
<td>178.8</td>
<td></td>
</tr>
<tr>
<td>Total revenues</td>
<td>€17,310.6</td>
<td>€18,976.7</td>
<td>€482.3</td>
<td></td>
</tr>
<tr>
<td>Cost of sales</td>
<td>(2,995.0)</td>
<td>(2,911.5)</td>
<td>(59.3)</td>
<td></td>
</tr>
<tr>
<td>Research and development expenses</td>
<td>(1,537.0)</td>
<td>(949.2)</td>
<td>(645.0)</td>
<td></td>
</tr>
<tr>
<td>Sales and marketing expenses</td>
<td>(59.5)</td>
<td>(50.4)</td>
<td>(14.5)</td>
<td></td>
</tr>
<tr>
<td>General and administrative expenses</td>
<td>(484.7)</td>
<td>(285.8)</td>
<td>(94.1)</td>
<td></td>
</tr>
<tr>
<td>Other operating expenses</td>
<td>(407.0)</td>
<td>(94.4)</td>
<td>(2.4)</td>
<td></td>
</tr>
<tr>
<td>Other operating income</td>
<td>815.3</td>
<td>596.4</td>
<td>250.5</td>
<td></td>
</tr>
<tr>
<td><strong>Operating income / (loss)</strong></td>
<td><strong>€12,642.7</strong></td>
<td><strong>€15,283.8</strong></td>
<td><strong>€82.4</strong></td>
<td></td>
</tr>
<tr>
<td>Finance income</td>
<td>330.3</td>
<td>67.7</td>
<td>1.6</td>
<td></td>
</tr>
<tr>
<td>Finance expenses</td>
<td>(18.9)</td>
<td>(305.1)</td>
<td>(65.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Profit (loss) before tax</strong></td>
<td><strong>€12,954.4</strong></td>
<td><strong>€15,046.4</strong></td>
<td><strong>€(145.8)</strong></td>
<td></td>
</tr>
<tr>
<td>Income taxes</td>
<td>(1,519.7)</td>
<td>(1,735.9)</td>
<td>(161.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Profit for the period</strong></td>
<td><strong>€9,434.4</strong></td>
<td><strong>€13,310.5</strong></td>
<td><strong>€15.2</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Earnings per share**

- Basic profit for the period per share: €38.78, €42.18, €0.06
- Diluted profit for the period per share: €37.77, €39.63, €0.06
Comparison of the year ended December 31, 2022 and the year ended December 31, 2021

Revenues

The following is a summary of revenues recognized for the periods indicated:

<table>
<thead>
<tr>
<th></th>
<th>Years ended December 31,</th>
<th>Change</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2022</td>
<td>2021</td>
<td>€</td>
</tr>
<tr>
<td><strong>Revenues</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial revenues</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COVID-19 vaccine revenues</td>
<td>17,145.2</td>
<td>18,806.8</td>
<td>(1,661.6)</td>
</tr>
<tr>
<td>Sales to collaboration partners(1)</td>
<td>1,224.3</td>
<td>970.9</td>
<td>253.4</td>
</tr>
<tr>
<td>Direct product sales to customers</td>
<td>3,184.7</td>
<td>3,007.2</td>
<td>177.5</td>
</tr>
<tr>
<td>Share of collaboration partners’ gross profit and sales milestones</td>
<td>12,736.2</td>
<td>14,828.7</td>
<td>(2,092.5)</td>
</tr>
<tr>
<td><strong>Other sales</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>49.4</td>
<td>67.2</td>
<td>(17.8)</td>
</tr>
<tr>
<td><strong>Research &amp; development revenues from collaborations</strong></td>
<td>116.0</td>
<td>182.7</td>
<td>66.7</td>
</tr>
<tr>
<td><strong>Total revenues</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>17,310.6</td>
<td>18,976.7</td>
<td>(1,666.1)</td>
</tr>
</tbody>
</table>

(1) Represents sales to our collaboration partners of products manufactured by us and reflects manufacturing costs and variances to the extent identified.

Commercial Revenues

From the year ended December 31, 2021 compared to the year ended December 31, 2022 commercial revenues decreased by €1,679.4 million from €18,874.0 million to €17,194.6 million, mainly due to the slightly decreased demand for our COVID-19 vaccine. 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. Submissions to pursue regulatory approvals in those countries where emergency use authorizations or equivalents were initially granted are ongoing. Pfizer has marketing and distribution rights worldwide with the exception of China, Germany and Turkey. 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-offs of inventories as well as costs related to production capacities derived from contracts with Contract Manufacturing Organizations (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 adjustment once identified and assessed highly probable. Sales to collaboration partners during the years ended December 31, 2022, and 2021, amounted to €1,224.3 million and €970.9 million, respectively. During the years ended December 31, 2022, and 2021 those sales included €850.0 million and €31.0 million, respectively, related to the aforementioned manufacturing variances.

By supplying our territories during the years ended December 31, 2022, and 2021, we recognized €3,184.7 million and €3,007.2 million of revenues, respectively, from direct COVID-19 vaccine sales in Germany and Turkey. 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 net figure and is recognized as collaboration revenue during the commercial phase, together with sales milestones that are recorded once the underlying thresholds are met. When determining the gross profit, manufacturing cost variances either reflected as transfer price adjustment as described above, or resulting from costs highly probable to be incurred by the partner were considered. During the year ended December 31, 2022, €12,736.2 million gross profit share has been recognized as revenue. During the year ended December 31, 2021, €14,352.1 million gross profit share and €476.6 million of sales milestones have been recognized as revenues.
Research & Development Revenues from Collaborations

From the year ended December 31, 2021 compared to the year ended December 31, 2022, research and development revenues from collaborations increased by €13.3 million or 13% from €102.7 million to €116.0 million. This was mainly derived from our collaborations with Pfizer and Sanofi S.A., or Sanofi.

Cost of Sales

The following table summarizes our cost of sales for the periods indicated:

<table>
<thead>
<tr>
<th>(in millions)</th>
<th>Years ended December 31</th>
<th>Change</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of sales</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of sales related to COVID-19 vaccine revenues</td>
<td>€2,960.1</td>
<td>€2,855.6</td>
<td>€104.5</td>
</tr>
<tr>
<td>Cost related to other sales</td>
<td>34.9</td>
<td>33.9</td>
<td>(1.0)</td>
</tr>
<tr>
<td>Total cost of sales</td>
<td>€3,095.0</td>
<td>€2,991.5</td>
<td>€103.5</td>
</tr>
</tbody>
</table>

From the year ended December 31, 2021 to the year ended December 31, 2022, cost of sales increased by €83.5 million or 3% from €2,911.5 million to €2,995.0 million, mainly due to recognizing cost of sales from our 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 Contract Manufacturing Organizations, or CMOs, that became redundant. The effects were driven by the introduction of a new COVID-19 vaccine formulation, the switch from the monovalent vaccine to our Omicron-adapted bivalent COVID-19 vaccines and due to accelerating internal manufacturing capacities during the year ended December 31, 2022.

Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated:

<table>
<thead>
<tr>
<th>(in millions)</th>
<th>Years ended December 31</th>
<th>Change</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and development expenses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchased services</td>
<td>€621.6</td>
<td>€572.6</td>
<td>€49.0</td>
</tr>
<tr>
<td>Wages, benefits and social security expense</td>
<td>385.9</td>
<td>233.1</td>
<td>152.8</td>
</tr>
<tr>
<td>Laboratory supplies</td>
<td>398.0</td>
<td>53.8</td>
<td>344.2</td>
</tr>
<tr>
<td>Depreciation and amortization</td>
<td>49.3</td>
<td>32.9</td>
<td>16.4</td>
</tr>
<tr>
<td>Other</td>
<td>82.2</td>
<td>56.8</td>
<td>25.4</td>
</tr>
<tr>
<td>Total research and development expenses</td>
<td>€1,537.0</td>
<td>€949.2</td>
<td>€587.8</td>
</tr>
</tbody>
</table>

From the year ended December 31, 2021 to the year ended December 31, 2022, our research and development expenses increased by €587.8 million or 62% from €949.2 million to €1,537.0 million, mainly due to expenses in connection with the development and production of our Omicron-adapted bivalent COVID-19 vaccines and from progressing the clinical studies for our pipeline candidates. The increase was further driven by an increase in wages, benefits and social security expenses resulting from an increase in headcount as well as expenses incurred under our share-based-payment arrangements.
Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses for the periods indicated:

<table>
<thead>
<tr>
<th>(in millions)</th>
<th>Years ended December 31</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales and marketing expenses</td>
<td>2022</td>
<td>2021</td>
</tr>
<tr>
<td>Purchased services</td>
<td>€24.0</td>
<td>€26.5</td>
</tr>
<tr>
<td>IT costs</td>
<td>11.2</td>
<td>5.0</td>
</tr>
<tr>
<td>Wages, benefits and social security expense</td>
<td>7.8</td>
<td>4.3</td>
</tr>
<tr>
<td>Other</td>
<td>16.5</td>
<td>14.6</td>
</tr>
<tr>
<td>Total sales and marketing expenses</td>
<td>€59.5</td>
<td>€50.4</td>
</tr>
</tbody>
</table>

From the year ended December 31, 2021 to the year ended December 31, 2022, our sales and marketing expenses increased by €9.1 million or 18% from €50.4 million to €59.5 million, mainly due to increased expenses for IT consulting and an increase in wages, benefits and social security expenses resulting from an increase in headcount.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the periods indicated:

<table>
<thead>
<tr>
<th>(in millions)</th>
<th>Years ended December 31</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>General and administrative expenses</td>
<td>2022</td>
<td>2021</td>
</tr>
<tr>
<td>Wages, benefits and social security expense</td>
<td>€145.9</td>
<td>€90.5</td>
</tr>
<tr>
<td>Purchased services</td>
<td>143.9</td>
<td>70.2</td>
</tr>
<tr>
<td>IT and office equipment</td>
<td>88.1</td>
<td>25.1</td>
</tr>
<tr>
<td>Insurance premiums</td>
<td>21.3</td>
<td>30.4</td>
</tr>
<tr>
<td>Other</td>
<td>85.5</td>
<td>69.6</td>
</tr>
<tr>
<td>Total general and administrative expenses</td>
<td>€484.7</td>
<td>€285.8</td>
</tr>
</tbody>
</table>

From the year ended December 31, 2021 to the year ended December 31, 2022, our general and administrative expenses increased by €198.9 million or 70% from €285.8 million to €484.7 million, mainly due to increased expenses for IT consulting and IT services, increased expenses for purchased management consulting and legal services as well as an increase in wages, benefits and social security expenses resulting mainly from an increase in headcount. Our business development transactions also contributed to the increase in general and administrative expenses.
### Other Operating Income / Expenses

The following table summarizes our other result, including other operating income and expenses, for the periods indicated:

<table>
<thead>
<tr>
<th></th>
<th>Years ended December 31,</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2022 (in millions)</td>
<td>2021</td>
</tr>
<tr>
<td>Other operating result</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other operating income</td>
<td>€ 815.3</td>
<td>€ 598.4</td>
</tr>
<tr>
<td>Foreign exchange differences, net</td>
<td>727.4</td>
<td>466.3</td>
</tr>
<tr>
<td>Government grants</td>
<td>1.4</td>
<td>1.5</td>
</tr>
<tr>
<td>Gain on derivative instruments at fair value through profit or loss</td>
<td>—</td>
<td>5.7</td>
</tr>
<tr>
<td>Other</td>
<td>86.5</td>
<td>9.2</td>
</tr>
<tr>
<td>Other operating expenses</td>
<td>(€407.0)</td>
<td>(€94.4)</td>
</tr>
<tr>
<td>Loss on derivative instruments at fair value through profit or loss</td>
<td>(385.5)</td>
<td>(86.3)</td>
</tr>
<tr>
<td>Other</td>
<td>(21.5)</td>
<td>(8.1)</td>
</tr>
<tr>
<td>Total other operating result</td>
<td>€ 408.3</td>
<td>€ 504.0</td>
</tr>
</tbody>
</table>

From the year ended December 31, 2021 to the year ended December 31, 2022, our total other result decreased by €95.7 million or 19% from €504.0 million to €408.3 million. The other operating result reflected the change in foreign exchange rates and included increased foreign exchange differences that related to 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. The amounts were offset by 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.

### Finance Income / Expenses

The following table summarizes our finance result for the periods indicated:

<table>
<thead>
<tr>
<th></th>
<th>Years ended December 31,</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2022 (in millions)</td>
<td>2021</td>
</tr>
<tr>
<td>Finance result</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finance income</td>
<td>€330.3</td>
<td>€67.7</td>
</tr>
<tr>
<td>Fair value adjustments of financial instruments measured at fair value</td>
<td>216.8</td>
<td>—</td>
</tr>
<tr>
<td>Interest income</td>
<td>48.5</td>
<td>1.5</td>
</tr>
<tr>
<td>Finance expenses</td>
<td>(€18.9)</td>
<td>(€305.1)</td>
</tr>
<tr>
<td>Interest expenses related to financial assets</td>
<td>(11.1)</td>
<td>(2.5)</td>
</tr>
<tr>
<td>Interest expenses related to lease liabilities</td>
<td>(5.1)</td>
<td>(2.9)</td>
</tr>
<tr>
<td>Amortization of financial instruments</td>
<td>(2.7)</td>
<td>(21.9)</td>
</tr>
<tr>
<td>Fair value adjustments of financial instruments measured at fair value</td>
<td>(277.8)</td>
<td>277.8</td>
</tr>
<tr>
<td>Total finance result</td>
<td>(€311.4)</td>
<td>(€237.4)</td>
</tr>
</tbody>
</table>

From the year ended December 31, 2021 to the year ended December 31, 2022, our total financial result increased by €548.8 million from a negative financial result of €237.4 million to a positive financial result of €311.4 million, mainly due to the change in fair value measurement adjustments of the derivative embedded within the convertible note. In February...
2022 we gave notice to Temasek (Ellington Investments Pte. Ltd.), or Temasek, that we would exercise our early redemption option and fully redeemed the convertible note on March 1, 2022 (see the description of “Liquidity and Capital Resources” in this Item 5 of this Annual Report as well as in Note 12 of our consolidated financial statements included elsewhere in this Annual Report). The fair value measurement adjustments which led to finance expenses during the year ended December 31, 2021 and finance income during the year ended December 31, 2022 were mainly driven by our share price development during the time up until redemption.

Income Taxes

The following table summarizes our income taxes for the periods indicated:

<table>
<thead>
<tr>
<th></th>
<th>Years ended</th>
<th>Change</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>December 31,</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2022 (in millions)</td>
<td>2021 (in millions)</td>
<td>€</td>
</tr>
<tr>
<td>Current income taxes</td>
<td>€3,629.6</td>
<td>€4,535.0</td>
<td>€(905.4)</td>
</tr>
<tr>
<td>Deferred taxes</td>
<td>(109.9)</td>
<td>218.9</td>
<td>€129.0</td>
</tr>
<tr>
<td>Income taxes</td>
<td>€3,519.7</td>
<td>€4,753.9</td>
<td>€1,234.2</td>
</tr>
</tbody>
</table>

Our current income taxes represent mainly corporate and trade taxes derived by our German tax group. The increase in profit during the year ended December 31, 2022 led to taxable income for the year ended December 31, 2022 for the German tax group. Corporate and trade tax charge will become due once tax declarations have been filed and assessed. For the year ended December 31, 2021 the German tax group incurred corporate and trade taxes.


As of December 31, 2022, we have not recognized deferred tax assets for unused tax losses and temporary differences at amount of €136.7 million (December 31, 2021: €81.0 million) as there is not sufficient probability in terms of IAS 12 that there will be future taxable income available against which the unused tax losses and temporary differences can be utilized.

These amounts included tax losses at an amount of €304.0 million U.S. federal tax losses and €184.6 million U.S. state tax losses (December 31, 2021: €238.1 million U.S. federal tax losses and €147.4 million U.S. state tax losses) related to the US tax group, thereof €240.0 million U.S. federal losses and thereof €179.0 million U.S. state tax losses that begin to expire at various dates beginning in 2033. All other material unused tax losses and temporary differences can be carried forward indefinitely.

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.

Comparison of the year ended December 31, 2021 and the year ended December 31, 2020

For a discussion of our operating results for the year ended December 31, 2020 and a comparison of the years ended December 31, 2021, and 2020 please refer to Item 5 of our Annual Report on Form 20-F for the year ended December 31, 2021, as amended.

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, 2022, and 2021 are explained in Item 7. of this Annual Report as well as in Note 20 of our consolidated financial statements included elsewhere in this Annual Report.

Impact of COVID-19

As we advance our clinical programs, we are in close contact with our principal investigators and clinical sites, and are assessing the impact on the clinical trials, expected timelines and costs on an ongoing basis. For certain programs, including BNT111, BNT113, BNT122, and BNT161 (Influenza), we experienced delays in the commencement of trials due to slowed patient enrolment and other delays as a result of the COVID-19 pandemic between 2020 and 2022. After several months of delay to focus efforts on our COVID-19 vaccine in 2020 and 2021, we started multiple Phase 1 and 2 clinical trials in 2021 and beyond. The initial delays, even though they were temporary, may negatively impact our operations and overall business by delaying further progress of these clinical trials and preclinical studies. Our operations, including research and manufacturing, could also be negatively impacted due to the potential impact of staff absences as a result of self-isolation procedures or extended illness. Such factors were evaluated and considered when preparing this Annual Report for the year ended December 31, 2022. We will continue to evaluate observed and potential effects of the COVID-19 pandemic.

COVID-19 Collaborations

In response to the COVID-19 pandemic, we initiated our COVID-19 vaccine development program in late January 2020, leveraging our proprietary mRNA platform, and assembled a global consortium of partners including Pfizer (worldwide collaboration outside of China) and Fosun Pharma (China).

Details about our COVID-19 collaborations are described further in Items 4 and 5 as well as the notes to our consolidated financial statements included elsewhere in this Annual Report.

Key Performance Indicators

Financial key performance indicators

The following financial performance indicators are in the focus of our operational business development management:

Commercial COVID-19 vaccine revenues

These revenues include, expected revenues related to our share of gross profit from sales by our collaboration partners in territories allocated to them based on marketing and distribution rights; expected revenues from direct COVID-19 vaccine sales to customers in our territories; and expected revenues from sales to our collaboration partners of products manufactured by us. Revenue is heavily influenced by the volumes available under the collaboration and the agreed upon purchase quantities and serves as a performance indicator of our current commercial profitability. We use this measure based on current exchange rates (not currency adjusted).

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. We use this measure based on current exchange rates (not currency-adjusted).

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 coordinative functions associated with the expansion of research and development, such as finance, human resources, or business development, with regard to the associated cost development. We use this key figure on the basis of current exchange rates (not currency-adjusted).

167
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.

Annual effective income tax rate

The effective income tax rate is an important parameter as part of profitability and liquidity planning.

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. On the research and development (R&D) front, we are focused on developing next generation COVID-19 vaccines to maintain leadership and pandemic preparedness as well as broaden the label of and access to the vaccine. We also plan to invest heavily to build out our global development organization, bringing in talent with clinical and regulatory expertise needed to rapidly advance our diversified clinical pipeline. 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 of December 31, 2022, we had cash and cash equivalents of €13,875.1 million. When analyzing our liquidity, we anticipate certain significant balance sheet items that are expected to improve our cash and cash equivalents balance subsequent to the end of the reporting period. Our trade receivables remained outstanding as of December 31, 2022 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, 2022, our trade receivables included, in addition to the profit share for the fourth quarter of 2022, trade receivables which related to the gross profit share for the third quarter of 2022. The payment settling our gross profit share for the third quarter of 2022 (as defined by the contract) in the amount of €1,816.5 million was received from our collaboration partner subsequent to the end of the reporting period as of January 12, 2023.

Cash and cash equivalents 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 short-term investments, including time deposits and money market funds (“MMF”) with an original maturity of three months or less, which are stated at fair value.

In July 2020, we offered 5,500,000 ADSs each representing one of our ordinary shares, in a public, underwritten offering on the Nasdaq Global Select Market at a public offering price of $93.00 per ADS, or the Underwritten Offering. In August 2020, following the Underwritten Offering, we issued 16,124 ADSs each representing one of our ordinary shares, in a rights offering at the same public offering price of $93.00 per ADS, or the Rights Offering. The Underwritten Offering and the Rights Offering were part of a single, global offering which we refer to as the Global Offering. The gross proceeds of the Global Offering were $513.0 million (€436.3 million).

A fund associated with Temasek (Ellington Investments Pte. Ltd.), or Temasek, and another accredited investor participated in a private investment which we refer to as the June 2020 Private Placement. The private placement included...
an investment in a four-year mandatory convertible note and an investment in ordinary shares. The €100.0 million four-year mandatory convertible note with a coupon of 4.5% per annum and a conversion premium of 20% above the reference price was early redeemed during the year ended December 31, 2022. In April 2022, the early redemption was fulfilled by issuing 1,744,392 ordinary shares (see Notes 12 and 15 to our consolidated financial statements included elsewhere in this Annual Report).

In November 2020, we entered into a sales agreement, or the Sales Agreement, with Jefferies LLC and SVB Leerink LLC (now known 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, 2021, 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 ADSs during year ended December 31, 2022. As of December 31, 2022, the remaining capacity under the Sales Agreement is still $207.1 million. Under the at-the-market offering program ADSs are sold via the stock exchange and therefore no shareholders’ subscription rights are affected.

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 (see Note 15 to our consolidated financial statements included elsewhere in this Annual Report).

In March 2022, our Management Board and Supervisory Board authorized a share repurchase program of ADSs, pursuant to which we may repurchase ADSs in the amount of up to $1.5 billion over the next two years. On May 2, 2022, the first tranche of our share repurchase program of ADSs, with a value of up to $0.5 billion, commenced. In November 2022, our Management Board and Supervisory Board authorized the second tranche of our share repurchase program of ADSs, with a value of up to $0.5 billion, commencing on December 7, 2022. During the year ended December 31, 2022, ADSs were repurchased at an average price of $143.98, for total consideration of $1.0 billion (€986.4 million). Repurchased ADSs were used to satisfy settlement obligations under our share-based payment arrangements.

In June 2022, at the Annual General Meeting, our shareholders approved a 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.

New Share Repurchase Program 2023

We expect our Management Board and Supervisory Board to authorize a share repurchase program of ADSs, pursuant to which we may repurchase ADSs in the amount of up to $0.5 billion during the year 2023. We expect to use all or a portion of the ADSs we repurchase and hold in treasury to satisfy upcoming settlement obligations under our share-based payment arrangements.

Cash Flow

The following table summarizes the primary sources and uses of cash for each period presented:

<table>
<thead>
<tr>
<th>Years ended December 31,</th>
<th>2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net cash flows from (used in):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating activities</td>
<td>€13,577.4</td>
<td>€899.7</td>
<td>(€13.5)</td>
</tr>
<tr>
<td>Investing activities</td>
<td>(35.3)</td>
<td>(566.1)</td>
<td>(144.8)</td>
</tr>
<tr>
<td>Financing activities</td>
<td>(1,419.3)</td>
<td>96.2</td>
<td>894.7</td>
</tr>
<tr>
<td>Total cash inflow</td>
<td>€12,122.8</td>
<td>€417.8</td>
<td>€736.4</td>
</tr>
</tbody>
</table>

Operating Activities

We derive cash flows from operations primarily from collaborations, 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. 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. Therefore, subsequent to the end of the reporting period, in January 2023, we further improved our cash position as we received the settlement payment of our gross profit share for the third quarter of 2022 (as defined by the contract).
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, 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, 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 finance expenses related to our convertible bond fair value update which were offset by net foreign exchange differences and movements in government grants. The net negative change in assets and liabilities was primarily due to an increase in trade receivables related to our COVID-19 collaboration with Pfizer.

Net cash used in operating activities for the year ended December 31, 2020 was €13.5 million, comprising a loss before tax of €145.8 million, positive non-cash adjustments of €227.1 million, and a net negative change in assets and liabilities of €93.1 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, 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.

Net cash used in investing activities for the year ended December 31, 2020 was €144.8 million, of which €66.0 million was attributable to the purchase of property, plant and equipment and €80.6 million were mainly attributable to the acquisition of our new manufacturing facility in Marburg, Germany.

Financing Activities

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 €984.2 million, primarily generated from the sale of treasury shares under the at-the-market offering program net of transaction cost, as described in Note 15 to the consolidated financial statements included elsewhere in this Annual Report and offset by the amount spent when repaying our financing arrangement which was entered with the European Investment Bank, or the EIB.
Net cash generated in financing activities for the year ended December 31, 2020 was €894.7 million, primarily generated from proceeds from the issuance of shares in the amount of €753.0 million and proceeds from loans and borrowings in the amount of €156.0 million, partially offset by the payment of lease liabilities in the amount of €12.7 million.

**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 expansion of sites in Germany and new sites in the United States, and potentially others 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 2023 is related to lease payments amounting to €40.5 million and CMO purchase obligations amounting to €41.4 million. Further, we have lease payment obligation with an amount of €192.0 million and purchase obligations of €55.2 million for the years 2024 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 collaboration;
• 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.

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

Management Board (Vorstand)

During the year ended December 31, 2022, there were no changes to the composition of our Management Board and service agreements with Prof. Ugur Sahin, M.D., Sean Marett, Ryan Richardson and Prof. Özlem Türeci, M.D. were renewed. Following such renewals, all service agreements with current Management Board members have terms with end dates that fall between December 31, 2024 and December 31, 2026.
The following table sets forth the names and functions of the current members of our Management Board, their ages as of December 31, 2022 and their terms:

<table>
<thead>
<tr>
<th>Name</th>
<th>Age</th>
<th>Term Expires</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prof. Ugur Sahin, M.D.</td>
<td>57</td>
<td>2026</td>
<td>Chief Executive Officer</td>
</tr>
<tr>
<td>Jens Holstein</td>
<td>59</td>
<td>2025</td>
<td>Chief Financial Officer</td>
</tr>
<tr>
<td>Sean Marett</td>
<td>57</td>
<td>2024</td>
<td>Chief Business Officer and Chief Commercial Officer</td>
</tr>
<tr>
<td>Sercet Poetting, Ph.D.</td>
<td>49</td>
<td>2026</td>
<td>Chief Operating Officer</td>
</tr>
<tr>
<td>Ryan Richardson</td>
<td>43</td>
<td>2026</td>
<td>Chief Strategy Officer</td>
</tr>
<tr>
<td>Prof. Özlem Türeci, M.D.</td>
<td>55</td>
<td>2025</td>
<td>Chief Medical Officer</td>
</tr>
</tbody>
</table>

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 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 (W3) in Translational Oncology & Immunology at Johannes Gutenberg University in Mainz, Germany, where he was the supervisor for more than 50 Ph.D. students. He also holds the role of Chair of the Scientific Management Board of the Helmholtz Institute for Translational Oncology (HI-TRON), also in Mainz. 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, 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 ProServ 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. (Nasdaq:VCYT), a listed company.

**Sean Marett** is our Chief Business Officer and Chief Commercial Officer. He joined BioNTech in 2012. Prior to joining BioNTech, 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 Lorraine. 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 NexPharma. Sean Marett has been Chair of PHMB Ltd, a company specializing in market access and pharmaceutical reimbursement, since 2017. He became a member of the supervisory board of ACardis AG in February 2021. 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 and 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, he 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 Richardson joined BioNTech in 2018 as the 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 and Vice President 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 for five years as a Management Consultant to biopharmaceutical companies in the U.S. and Europe, focusing on strategic and operational projects in the areas of commercial strategy, pricing and market access, new product planning, and R&D transformation. Ryan 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.

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 “Project Lightspeed.” She previously served as CEO and Chief Medical Officer of Ganymed Pharmaceuticals AG, which she co-founded with Ugur Sahin and Prof. Christoph Huber, M.D. The company was acquired by Astellas in 2016. 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 recent recipient of the German Sustainability Award, among other notable recognitions. Özlem Türeci is married to Ugur Sahin.

Supervisory Board (Aufsichtsrat)

In 2022, we expanded our Supervisory Board by appointing Prof. Anja Morawietz, Ph.D. and Prof. Rudolf Staudigl, Ph.D. in our Annual General Meeting on June 1, 2022. Helmut Jeggle was reappointed as a Supervisory Board member in such Annual General Meeting and was re-elected by the Supervisory Board as its Chair in a meeting following the Annual General Meeting. Helmut Jeggle’s, Anja Morawietz’s and Rudolf Staudigl’s current appointment to our Supervisory Board will end upon the Annual General Meeting in 2026.
The following table sets forth the names and functions of the current members of our Supervisory Board, their ages as of December 31, 2022, their terms (which expire on the date of the relevant year’s general shareholders’ meeting) and their principal occupations outside of our Company:

<table>
<thead>
<tr>
<th>Name</th>
<th>Age</th>
<th>Term Expires</th>
<th>Principal Occupation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Helmut Jeggle (Chair Supervisory Board)</td>
<td>52</td>
<td>2026</td>
<td>Managing partner and entrepreneurial venture capital investor of Salvia GmbH (Supervisory Board member 4SC AG, AiCuris AG, AFFiRiS AG, APK AG and Tonies SE)</td>
</tr>
<tr>
<td>Ulrich Wandschneider, Ph.D. (Deputy Chair Supervisory Board)</td>
<td>61</td>
<td>2023</td>
<td>Managing director of bherbusy capital GmbH and independent consultant to companies in thelife science and healthcare sector (from January 1 till December 31, 2021 Supervisory Board member Vanguard AG)</td>
</tr>
<tr>
<td>Prof. Christoph Huber, M.D. (Supervisory Board member)</td>
<td>78</td>
<td>2023</td>
<td>Professor emeritus at the Johannes-Gutenberg University Mainz (Deputy Chair of the Supervisory Board Tirol Kliniken GmbH)</td>
</tr>
<tr>
<td>Prof. Anja Morawietz, Ph.D. (Supervisory Board member)</td>
<td>45</td>
<td>2026</td>
<td>Certified Public Accountant and Management Consultant, Professor of External Accounting and General Business Administration at the Nuremberg University of Applied Sciences Georg Simon Ohm</td>
</tr>
<tr>
<td>Michael Motschmann (Supervisory Board member)</td>
<td>65</td>
<td>2023</td>
<td>Member of the Management Board and head of equity investments of MB Capital AG (Supervisory Board member AFFiRiS AG, APK AG, HMW-Emissionshaus AG and HMW-Innovations AG)</td>
</tr>
<tr>
<td>Prof. Rudolf Staudigl, Ph.D. (Supervisory Board member)</td>
<td>68</td>
<td>2026</td>
<td>Independent consultant (member of the Supervisory Board of TÜV Süd Aktiengesellschaft, member of the Supervisory Board of Groz-Beckert KG (Deputy Chair))</td>
</tr>
</tbody>
</table>

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:

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: TNE).

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 Mediclin AG later of Asklepios Kliniken GmbH & Co. KGaA. He currently serves on various supervisory and advisory boards.

Prof. 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 35 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. She also works as a freelance auditor, particularly in audit-related consulting. Previously, she worked for ten years for auditing company KPMG, 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, she 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 Chemetronic 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 Chemetronic 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**

**Remuneration of Our Supervisory Board Members**

The remuneration system of our Supervisory Board as included in our Articles of Association is structured as 100% fixed compensation. While retaining the system for the compensation of Supervisory Board members, the compensation of Supervisory Board members was slightly increased during the year ended December 31, 2022 to account for additional workload. The new provisions were approved by the Annual General Meeting on June 1, 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.

Hence, for the members of the Supervisory Board who joined in 2022, namely Anja Morawietz and Rudolf Staudigl, the remuneration was applied on a pro-rata basis from July 5, 2022, the date of entry of the corresponding amendment to the Articles of Association in our Commercial Register.

Retroactively, from January 1, 2022, 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 shall receive an additional annual compensation of €30,000. The respective Chair of another committee shall receive an additional annual compensation of €15,000. An ordinary committee member shall receive an additional annual remuneration of €5,000 per committee.
All members of the Supervisory Board are reimbursed for their expenses.

<table>
<thead>
<tr>
<th>Year</th>
<th>Helmut Jeggle</th>
<th>Ulrich Wandschneider, Ph.D.</th>
<th>Prof. Christoph Huber, M.D.</th>
<th>Prof. Anja Morawietz, Ph.D.</th>
<th>Michael Motschmann</th>
<th>Prof. Rudolf Staudigl, Ph.D.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2022</td>
<td>€ 210</td>
<td>€ 105</td>
<td>€ 70</td>
<td>€ 35</td>
<td>€ 70</td>
<td>€ 35</td>
</tr>
<tr>
<td>2021</td>
<td>€ 177</td>
<td>€ 88</td>
<td>€ 59</td>
<td>—</td>
<td>€ 59</td>
<td>—</td>
</tr>
</tbody>
</table>

Committee Compensation

<table>
<thead>
<tr>
<th>Year</th>
<th>Helmut Jeggle</th>
<th>Ulrich Wandschneider, Ph.D.</th>
<th>Prof. Christoph Huber, M.D.</th>
<th>Prof. Anja Morawietz, Ph.D.</th>
<th>Michael Motschmann</th>
<th>Prof. Rudolf Staudigl, Ph.D.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2022</td>
<td>15</td>
<td>35</td>
<td>10</td>
<td>—</td>
<td>25</td>
<td>—</td>
</tr>
<tr>
<td>2021</td>
<td>4</td>
<td>24</td>
<td>—</td>
<td>—</td>
<td>4</td>
<td>—</td>
</tr>
</tbody>
</table>

Total

<table>
<thead>
<tr>
<th>Year</th>
<th>Helmut Jeggle</th>
<th>Ulrich Wandschneider, Ph.D.</th>
<th>Prof. Christoph Huber, M.D.</th>
<th>Prof. Anja Morawietz, Ph.D.</th>
<th>Michael Motschmann</th>
<th>Prof. Rudolf Staudigl, Ph.D.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2022</td>
<td>€ 225</td>
<td>€ 140</td>
<td>€ 80</td>
<td>€ 35</td>
<td>€ 95</td>
<td>€ 35</td>
</tr>
<tr>
<td>2021</td>
<td>€ 181</td>
<td>€ 112</td>
<td>€ 59</td>
<td>—</td>
<td>€ 63</td>
<td>—</td>
</tr>
</tbody>
</table>

Members of the Supervisory Board who are only members of the Supervisory Board for part of the financial year or who chair or vice-chair the Supervisory Board or the Audit Committee or another committee shall receive the respective compensation on a pro-rata basis. The same applies insofar as this regulation or this regulation in a specific version is only in force during part of the financial year.

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 Jeggle: 2026
- Ulrich Wandschneider: 2023
- Christoph Huber: 2023
- Anja Morawietz: 2026
- Michael Motschmann: 2023
- Rudolf Staudigl: 2026

Remuneration 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
The service agreements with our Management Board provide for a short-term incentive compensation which is an annual performance-related bonus for the years of their respective service periods. During the year ended December 31, 2021, the maximum short-term incentive compensation for Ugur Sahin, Sean Marett, Sierk Poetting, Ryan Richardson and Özlem Türeci was €180,000, €200,000, €180,000, €160,000 and €180,000 which, considering the 2021 target achievement of 100%, led to the respective annual bonus amounts for the year ended December 31, 2021. Following the effective extension of their respective service agreements, the maximum short-term incentive compensation for Sean Marett, Sierk Poetting and Özlem Türeci was increased to €350,000 and €300,000, respectively. Effective January 1, 2023, subsequent to the end of the reporting period covered by this Annual Report, Ryan Richardson’s annual fixed compensation was increased to €550,000. 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, 2022 and 2021, her effective annual fixed compensation amounted to €518,333 and €360,000 respectively.

The service agreements with our Management Board provide for a long-term incentive compensation which is an annual performance-related bonus for the years of their respective service periods. During the year ended December 31, 2021, the maximum short-term incentive compensation for Jens Holstein was defined as €300,000 which led to an effective annual bonus of €150,000 and €255,000 for the years ended December 31, 2021 and 2022, respectively. Effective as of his appointment to the Management Board on July 1, 2021, the maximum short-term incentive compensation for Jens Holstein was increased to €350,000 and €300,000, respectively. Fixed compensation was increased to €550,000. Starting with his appointment to the Management Board on July 1, 2021, the maximum short-term incentive compensation for Jens Holstein was defined as €300,000 which led to an effective annual bonus of €150,000 and €255,000 for the years ended December 31, 2021 and 2022, 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. 50% percent of the compensation are paid following the determination on 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).

The service agreements with our Management Board 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 will be 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 agreement thereunder. During the year ended December 31, 2021, the number of options granted to Ugur Sahin, Prof. Özlem Türeci, M.D., Jens Holstein, Sean Marett, Sierk Poetting, Ryan Richardson and Özlem Türeci was calculated based on a target value of €750,000, €300,000, €260,000 and €300,000, respectively. Following the renewal of their respective service agreements, the target value for the number of options to be granted each year to Jens Holstein, Sean Marett, Sierk Poetting, Ryan Richardson and Özlem Türeci was increased to €1,050,000 and €550,000, respectively. The number of options to be granted each year to Jens Holstein was based on a target value of €550,000, which was applied during the year ended December 31, 2022. During the year ended December 31, 2021, the number of options to be granted to Jens Holstein was calculated using a pro rata value of €275,000. In each case the target values are divided by the amount by which a certain target share price exceeds the exercise price.
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 for members of the Management Board was approved by the Annual General Meeting on June 22, 2021 and becomes effective whenever new service agreements are entered into, existing service agreements are extended or specific compensation components are initiated.

The comprehensive remuneration 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, 2022, and 2021, the members of our Management Board received the aggregate remuneration of €15.0 million and €20.4 million, respectively.

<table>
<thead>
<tr>
<th></th>
<th>Prof. Uğur Sahin, M.D.</th>
<th>Jens Holstein</th>
<th>Sean Marett</th>
<th>Sjaak Postema, Ph.D.</th>
<th>Ryan Richardson</th>
<th>Prof. Özlem Türeci, M.D.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fixed compensation</strong></td>
<td>€ 360</td>
<td>€ 550</td>
<td>€ 513</td>
<td>€ 550</td>
<td>€ 340</td>
<td>€ 518</td>
</tr>
<tr>
<td><strong>Fringe benefits</strong>(1)</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>4</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>3</td>
<td>22</td>
<td>4</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td><strong>Short-term incentive – first installment</strong></td>
<td>77</td>
<td>128</td>
<td>128</td>
<td>128</td>
<td>72</td>
<td>128</td>
</tr>
<tr>
<td></td>
<td>90</td>
<td>75</td>
<td>100</td>
<td>90</td>
<td>80</td>
<td>90</td>
</tr>
<tr>
<td><strong>Short-term incentive – second installment</strong>(2)</td>
<td>3</td>
<td>188</td>
<td>141</td>
<td>235</td>
<td>4</td>
<td>183</td>
</tr>
<tr>
<td></td>
<td>223</td>
<td>186</td>
<td>248</td>
<td>243</td>
<td>200</td>
<td>223</td>
</tr>
<tr>
<td><strong>Other performance-related variable compensation</strong>(4)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>—</td>
<td>60</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Share-based payments (incl. long-term incentive)</strong>(5)</td>
<td>5,866</td>
<td>863</td>
<td>1,507</td>
<td>1,550</td>
<td>69</td>
<td>809</td>
</tr>
<tr>
<td></td>
<td>10,907</td>
<td>869</td>
<td>1,709</td>
<td>1,977</td>
<td>517</td>
<td>454</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>€ 6,312</td>
<td>€ 1,736</td>
<td>€ 2,357</td>
<td>€ 2,467</td>
<td>€ 512</td>
<td>€1,638</td>
</tr>
<tr>
<td></td>
<td>€ 11,586</td>
<td>€ 1,408</td>
<td>€ 2,479</td>
<td>€ 2,690</td>
<td>€ 1,133</td>
<td>€1,127</td>
</tr>
</tbody>
</table>

(1) 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 of €800,000 by awarding 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.

(2) 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.
The fair value of the second installment of the short-term incentive compensation which has been classified as 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.

During the year ended December 31, 2022, as part of the extension of his service agreement, Sean Marett received a one-time signing and retention cash payment in the amount of €60,000.

The fair value of the share-based payments was determined pursuant to the regulations of IFRS 2 “Share-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 share options and other share-based payment instruments granted to our Management Board which are outstanding as of December 31, 2022 - excluding future grants:

<table>
<thead>
<tr>
<th>Grant Date / Allocation Date</th>
<th>Number of Ordinary Shares Underlying Options</th>
<th>Option Exercise Price (€)</th>
<th>Earliest Option Exercise Date</th>
<th>Option Expiration Date</th>
<th>Name of the Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>2/13/2020</td>
<td>97,420</td>
<td>28.32</td>
<td>2/13/2024</td>
<td>2/13/2030</td>
<td>LTI 2020 (1)</td>
</tr>
<tr>
<td>5/12/2021 (1)</td>
<td>17,780</td>
<td>173.66</td>
<td>5/12/2025</td>
<td>5/12/2031</td>
<td>LTI 2021 (1)</td>
</tr>
<tr>
<td>5/31/2022 (1)</td>
<td>19,897</td>
<td>142.60</td>
<td>5/31/2026</td>
<td>5/31/2022</td>
<td>LTI 2022 (1)</td>
</tr>
<tr>
<td>5/17/2021</td>
<td>6,463</td>
<td>175.16</td>
<td>5/17/2025</td>
<td>5/17/2031</td>
<td>LTI 2021 (1)</td>
</tr>
<tr>
<td>7/1/2021 (1)</td>
<td>4,246</td>
<td>n/a</td>
<td>7/1/2025</td>
<td>n/a</td>
<td>Signing Bonus</td>
</tr>
<tr>
<td>5/31/2022 (1)</td>
<td>14,664</td>
<td>142.60</td>
<td>5/31/2026</td>
<td>5/31/2022</td>
<td>LTI 2022 (1)</td>
</tr>
<tr>
<td>11/15/2018</td>
<td>230,780</td>
<td>10.14</td>
<td>11/15/2022</td>
<td>11/15/2026</td>
<td>ESOP 2018</td>
</tr>
<tr>
<td>2/13/2020</td>
<td>38,968</td>
<td>38.32</td>
<td>2/13/2024</td>
<td>2/13/2030</td>
<td>LTI 2020 (1)</td>
</tr>
<tr>
<td>5/12/2021 (1)</td>
<td>7,112</td>
<td>173.66</td>
<td>5/12/2025</td>
<td>5/12/2031</td>
<td>LTI 2021 (1)</td>
</tr>
<tr>
<td>5/31/2022 (1)</td>
<td>14,664</td>
<td>142.60</td>
<td>5/31/2026</td>
<td>5/31/2022</td>
<td>LTI 2022 (1)</td>
</tr>
<tr>
<td>11/15/2018</td>
<td>—</td>
<td>10.14</td>
<td>11/15/2022</td>
<td>11/15/2026</td>
<td>ESOP 2018</td>
</tr>
<tr>
<td>2/13/2020</td>
<td>38,968</td>
<td>38.32</td>
<td>2/13/2024</td>
<td>2/13/2030</td>
<td>LTI 2020 (1)</td>
</tr>
<tr>
<td>5/12/2021 (1)</td>
<td>7,112</td>
<td>173.66</td>
<td>5/12/2025</td>
<td>5/12/2031</td>
<td>LTI 2021 (1)</td>
</tr>
<tr>
<td>5/31/2022 (1)</td>
<td>14,664</td>
<td>142.60</td>
<td>5/31/2026</td>
<td>5/31/2022</td>
<td>LTI 2022 (1)</td>
</tr>
<tr>
<td>9/16/2018</td>
<td>—</td>
<td>10.14</td>
<td>9/16/2022</td>
<td>9/16/2026</td>
<td>ESOP 2018</td>
</tr>
<tr>
<td>2/13/2020</td>
<td>33,772</td>
<td>38.32</td>
<td>2/13/2024</td>
<td>2/13/2030</td>
<td>LTI 2020 (1)</td>
</tr>
<tr>
<td>5/12/2021 (1)</td>
<td>6,163</td>
<td>173.66</td>
<td>5/12/2025</td>
<td>5/12/2031</td>
<td>LTI 2021 (1)</td>
</tr>
<tr>
<td>5/31/2022 (1)</td>
<td>7,465</td>
<td>142.60</td>
<td>5/31/2026</td>
<td>5/31/2022</td>
<td>LTI 2022 (1)</td>
</tr>
<tr>
<td>11/15/2018</td>
<td>—</td>
<td>10.14</td>
<td>11/15/2022</td>
<td>11/15/2026</td>
<td>ESOP 2018</td>
</tr>
<tr>
<td>2/13/2020</td>
<td>38,968</td>
<td>38.32</td>
<td>2/13/2024</td>
<td>2/13/2030</td>
<td>LTI 2020 (1)</td>
</tr>
<tr>
<td>5/12/2021 (1)</td>
<td>7,112</td>
<td>173.66</td>
<td>5/12/2025</td>
<td>5/12/2031</td>
<td>LTI 2021 (1)</td>
</tr>
<tr>
<td>5/31/2022 (1)</td>
<td>14,664</td>
<td>142.60</td>
<td>5/31/2026</td>
<td>5/31/2022</td>
<td>LTI 2022 (1)</td>
</tr>
</tbody>
</table>

(1) 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 vest in four equal installments on October 9 of 2020, 2021, 2022 and 2023 but will not become exercisable before the expiry of the waiting period on October 9, 2023 and can only be exercised during the exercise windows as defined by our ESOP.

(3) Options vest in four equal installments on February 13 of 2021, 2022, 2023 and 2024 but will not become exercisable before 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 but Jens Holstein and May 17 of 2022, 2023, 2024 and 2025 for Jens Holstein. The options will not become exercisable before the expiry of the waiting period on May 12, 2025 and May 17, 2025, respectively.

181
Options were issued as phantom share options and vest in four equal installments on May 31, 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.

Initially granted options (610,110) fully vested on November 15, 2022. Options which remain outstanding (230,780) can only be exercised during the exercise windows as defined by our ESOP and if certain performance conditions are fulfilled as of the date the relevant option rights are exercised.

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 date does not exceed 800% of the exercise price. With respect to the ESOP 2018 and the CEO Grant 2019 agreements, the maximum economic benefit receivable in respect of any exercised option, is capped at $240.00. As a result, the effective exercise price will not increase above a Euro amount equivalent to $30.00. With respect to the LTI 2020 agreements, a value for the maximum cap mechanism may be determined by the Supervisory Board in the future. With respect to the phantom share options issued under the LTI 2021 and 2022 agreements, the maximum compensation that the Management Board members are entitled to receive under such agreements, 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.

As of July 1, 2021 when Jens Holstein was appointed to the Management Board as Chief Financial Officer (CFO), the Supervisory Board granted Jens Holstein a one-time signing bonus of €800,000 by awarding 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.

Indicates end of the respective waiting periods, additional restrictions with respect to exercise windows may apply.

Share-Based Payment Arrangements™
Management Board Grant (Long-Term Incentive)
The service agreements with our Management Board 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, phantom options equivalent to the number of options the Management Board members would have been entitled to receive for 2021 and 2022 were granted under the Management Board Grant. During 2021, the options were issued as phantom share options. As of December 31, 2022, the assessment of options expected to be allocated in future years was based on estimated allocation dates in the middle of the respective years.

For the awards allocated as of February 2020, the exercise price for each option is $30.78 (€28.32), calculated using the foreign exchange rate published by the German Central Bank (Deutsche Bundesbank) as of the grant date. The share options allocated as of February 2020 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. Our Supervisory Board reserves the right to limit the economic benefit from the exercise of the options to extend the result from extraordinary events or developments. For the awards allocated as of May 12, 2021, May 17, 2021, and May 31, 2022 the exercise prices are $185.23 (€173.66), $186.83 (€175.16) and $152.10 (€142.60), respectively (all amounts calculated as of December 31, 2022, using the foreign exchange rate as published by the German Central Bank (Deutsche Bundesbank)). 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. The phantom share options allocated as of May 2021 and 2022 are subject to the effective exercise price cap. In addition, the maximum compensation that the Management Board members are entitled to receive under those relevant agreements together with other compensation components received by each such board member in the respective grant year is capped at €20.0 million for Ugur Sahin as Chief Executive Officer (CEO) and €10.0 million for all other Management Board members. The options will vest annually in equal installments over four years commencing on the first anniversary of the allocation date and will be 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 starting on the fourth anniversary of the allocation date).
In September 2019, we granted Prof. Ugur Sahin, M.D. an option to purchase 4,374,963 of our ordinary shares, subject to Prof. 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, $15.00 ($13.60) 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 80% of the exercise price. Under the maximum cap mechanism, the maximum economic benefit receivable in respect of any exercised option, is capped at $240. As a result, the effective exercise price will not increase above a Euro amount equivalent to $30. The options will vest annually in equal installments after four years commencing on the first anniversary of our initial public offering and will be exercisable for four years after 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 subsequent 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 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 Prof. Ugur Sahin, M.D. an option to purchase 4,374,963 of our ordinary shares, subject to Prof. 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, $15.00 ($13.60) 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 80% of the exercise price. Under the maximum cap mechanism, the maximum economic benefit receivable in respect of any exercised option, is capped at $240. As a result, the effective exercise price will not increase above a Euro amount equivalent to $30. The options will vest annually in equal installments after four years commencing on the first anniversary of our initial public offering and will be exercisable for four years after 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 subsequent 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 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.

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 the participants a certain number of rights by explicit acceptance by the participants. The exercise of the 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, other than Ryan Richardson, who was not a Management Board member at the time the options were granted, the options are subject to the effective exercise price cap as well as 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 80% of the exercise price. Under the maximum cap mechanism, the maximum economic benefit receivable in respect of any exercised option, is capped at $240. As a result, the effective exercise price will not increase above a Euro amount equivalent to $30. The options (other than Prof. Özlem Türeci’s, M.D., and Ryan Richardson’s options) generally fully vest after four years and can only 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. Also, 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.
The Supervisory Board determined in September 2022 that the ESOP settlement in November and December 2022 would be made by delivery of 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 respective number of ADSs was settled with treasury shares.

During the year ended December 31, 2022, 5,152,410 option rights granted to our Management Board under the ESOP 2018 program vested and became exercisable (option rights allocated to Ryan Richardson and Özlem Türeci had already vested in 2019 but continued to be subject to performance and waiting requirements; Jens Holstein did not participate in the ESOP 2018 program as he had not joined our company at the time it was allocated). Of such vested option rights, 4,921,630 options were exercised during the year ended December 31, 2022 by paying the option exercise price of €19.78 weighted over the Management Board members (for all Management Board members, apart from Ryan Richardson who was not a Management Board member at the time the option rights were allocated, exercise prices are subject to the effective exercise price cap and the maximum cap mechanism as described further above). As of December 31, 2022, Sean Marett still holds 230,780 option rights which can only be exercised during the exercise windows as defined by our ESOP and if certain performance conditions are fulfilled as of the date the relevant option rights are exercised. The average closing price of an American Depositary Share of BioNTech on Nasdaq weighted over the Management Board’s settlement dates converted from USD to Euro using the exchange rate published by the German Central Bank (Deutsche Bundesbank) on the same days was €160.65.

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 internal monitoring system for risk management purposes.

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. In addition to Dr. Ulrich Wandschneider, the Supervisory Board considers Helmut Jeggle, Michael Motschmann and Prof. Christoph Huber, M.D. to be independent irrespective of the fact that they will soon have been members of the Supervisory Board for a period of more than 13 years. As stated in the declaration to the German Corporate Governance Code, or the Corporate Governance Code (Entsprechenserklärung) published by the Company on March 20, 2023 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, Ph.D., Prof. Anja Morawietz, Ph.D. and Prof. Rudolf Staudigl, Ph.D. 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 Mr. Helmut Jeggle as chairperson and Dr. 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, 2022. 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 already been evaluated and will subsequently be presented to the Supervisory Board. Based on the self-assessment, the Supervisory Board, 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 and Governance Committee and a Capital Markets Committee by resolution. Set forth in the table below are the members of the Audit Committee, the Compensation, Nominating and Corporate Governance Committee and the Capital Markets Committee during the year ended December 31, 2022.

As of January 1, 2023, the members of the Audit Committee, the Compensation, Nominating and Corporate Governance Committee and the Capital Markets Committee have been updated as set forth in the table below.

### Audit Committee
Our Audit Committee for the year ended December 31, 2022 consisted of Ulrich Wandschneider, Ph.D. (Chair), Prof. Christoph Huber, M.D. and Michael Motschmann. As of January 1, 2023, our Audit Committee comprises Anja Morawietz (Chair), Ulrich Wandschneider, Ph.D. and Prof. Rudolf Staudigl, Ph.D. 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 Corporate Governance Committee for the year ended December 31, 2022 consisted of Michael Motschmann (Chair), Prof. Christoph Huber, M.D. and Ulrich Wandschneider, Ph.D. As of January 1, 2023 our Compensation, Nominating and Corporate Governance Committee comprises Michael Motschmann (Chair), Prof. Christoph Huber, M.D. and Prof. Rudolf Staudigl, PhD. 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 those 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, 2022 consisted of Helmut Jeggle (Chair) and Michael Motschmann. As of January 1, 2023, our Capital Markets Committee comprises Helmut Jeggle (Chair), Michael Motschmann and Anja Morawietz. 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.

188
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. Prof. Ugur Sahin, M.D. 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 20 of each year;
- reporting to the Supervisory Board;
- all measures and transactions that require the Supervisory Board’s approval;
- all measures and transactions relating to a business area that is of extraordinary importance to us or involving an extraordinary economic risk;
- taking on new lines of business or discontinuing existing lines of business;
- acquisitions or sales of interests or holdings; and
- certain large transactions.

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, 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, 2022, we had 4,530 full-time equivalent employees working for us, of whom 830 hold a doctoral degree or higher. The following tables provide breakdowns of our full-time equivalent employees as per the periods indicated by function and by region:

<table>
<thead>
<tr>
<th>Function</th>
<th>December 31, 2022</th>
<th>December 31, 2021</th>
<th>December 31, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Research &amp; Development</td>
<td>245</td>
<td>143</td>
<td>117</td>
</tr>
<tr>
<td>Scientific Research &amp; Development</td>
<td>1,458</td>
<td>1,000</td>
<td>624</td>
</tr>
<tr>
<td>Operations</td>
<td>1,380</td>
<td>1,015</td>
<td>657</td>
</tr>
<tr>
<td>Quality</td>
<td>384</td>
<td>290</td>
<td>211</td>
</tr>
<tr>
<td>Supporting Functions</td>
<td>1,003</td>
<td>551</td>
<td>286</td>
</tr>
<tr>
<td>Commercial &amp; Business Development</td>
<td>140</td>
<td>83</td>
<td>45</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>4,530</strong></td>
<td><strong>3,082</strong></td>
<td><strong>1,941</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Region</th>
<th>December 31, 2022</th>
<th>December 31, 2021</th>
<th>December 31, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mainz, Germany (Headquarters)</td>
<td>2,041</td>
<td>1,712</td>
<td>1,161</td>
</tr>
<tr>
<td>Munich, Germany</td>
<td>98</td>
<td>71</td>
<td>45</td>
</tr>
<tr>
<td>Idar-Oberstein, Germany</td>
<td>441</td>
<td>348</td>
<td>254</td>
</tr>
<tr>
<td>Halle, Germany</td>
<td>25</td>
<td>17</td>
<td>9</td>
</tr>
<tr>
<td>Berlin, Germany</td>
<td>202</td>
<td>134</td>
<td>109</td>
</tr>
<tr>
<td>Marburg, Germany</td>
<td>648</td>
<td>546</td>
<td>268</td>
</tr>
<tr>
<td>Cambridge, United States</td>
<td>323</td>
<td>178</td>
<td>95</td>
</tr>
<tr>
<td>Gaithersburg, United States</td>
<td>111</td>
<td>59</td>
<td>—</td>
</tr>
<tr>
<td>Istanbul, Turkey</td>
<td>4</td>
<td>1</td>
<td>—</td>
</tr>
<tr>
<td>London, United Kingdom</td>
<td>15</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Singapore, Singapore</td>
<td>3</td>
<td>1</td>
<td>—</td>
</tr>
<tr>
<td>Shanghai, China</td>
<td>1</td>
<td>1</td>
<td>—</td>
</tr>
<tr>
<td>Vienna, Austria</td>
<td>20</td>
<td>17</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>4,530</strong></td>
<td><strong>3,082</strong></td>
<td><strong>1,941</strong></td>
</tr>
</tbody>
</table>

None of our employees has engaged in any labor strikes. We apply the federal collective bargaining agreements of the chemical industry at our Marburg site. Further, we maintain a couple of company agreements (Betriebsvereinbarungen) with respect to certain topics at our Idar-Oberstein, Mainz, Marburg and Berlin sites. We have a workers’ council at our Idar-Oberstein, Mainz, Marburg and Berlin (JPT Peptide Technologies GmbH) sites as well as a Group workers’ council (Konzernbetriebsrat). 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.

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table presents information, as of December 31, 2022 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, 2022 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 243,215,169 ordinary shares outstanding as of December 31, 2022. This amount excludes 5,337,031 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.
<table>
<thead>
<tr>
<th>Name of Beneficial Owner</th>
<th>Number of Shares Beneficially Owned</th>
<th>Percentage Beneficially Owned</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5% shareholders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AT Impf GmbH (1)</td>
<td>105,613,143</td>
<td>43.4%</td>
</tr>
<tr>
<td>Medine GmbH (2)</td>
<td>42,262,039</td>
<td>17.4%</td>
</tr>
<tr>
<td><strong>All 5% shareholders, as a group</strong></td>
<td><strong>147,875,182</strong></td>
<td><strong>60.8%</strong></td>
</tr>
<tr>
<td><strong>Members of the Supervisory Board and the Management Board</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prof. Ugur Sahin, M.D. (3)</td>
<td>42,262,039</td>
<td>17.4%</td>
</tr>
<tr>
<td>Jens Holstein</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Sean Marett (4)</td>
<td>938,140</td>
<td>(0)%</td>
</tr>
<tr>
<td>Sierk Poetting, Ph.D.(5)</td>
<td>739,784</td>
<td>(0)%</td>
</tr>
<tr>
<td>Ryan Richardson</td>
<td>14,523</td>
<td>(0)%</td>
</tr>
<tr>
<td>Prof. Özlem Türeci, M.D.</td>
<td>913,247</td>
<td>(0)%</td>
</tr>
<tr>
<td>Helmut Jeggle (6)</td>
<td>1,525,967</td>
<td>(0)%</td>
</tr>
<tr>
<td>Ulrich Wandschneider, Ph.D. (7)</td>
<td>1,480</td>
<td>1.1%</td>
</tr>
<tr>
<td>Prof. Christoph Huber, M.D. (7)</td>
<td>2,613,019</td>
<td>1.1%</td>
</tr>
<tr>
<td>Prof. Anja Morawietz, Ph.D(9)</td>
<td>240</td>
<td>(0)%</td>
</tr>
<tr>
<td>Michael Motschmann</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Prof. Rudolf Standig, Ph.D.</td>
<td>400</td>
<td>(0)%</td>
</tr>
<tr>
<td><strong>All members of our Supervisory Board and Management Board, as a group</strong></td>
<td><strong>49,008,839</strong></td>
<td><strong>20.2%</strong></td>
</tr>
</tbody>
</table>

(1) Information herein is based upon a Schedule 13G jointly filed with the SEC on February 14, 2023 by ATHOS KG, AT Impf GmbH and Thomas Maier. Consists of 105,613,143 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 enabled it to exercise the majority of voting rights to pass resolutions at our Annual General Meeting, or AGM. As of December 31, 2022 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 jointly filed with the SEC on February 21, 2023 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 42,262,039 ordinary shares held by Medine GmbH, 2,394,463 of which are held for 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. Prof. Sahin 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) 1,424 ordinary shares held directly by Sierk Poetting and (c) 230,780 ADSs issuable upon the exercise of option rights that are vested as of December 31, 2022 or exercisable within 60 days thereafter (subject to the exercise windows as defined by our ESOP and if certain performance conditions are fulfilled as of the date the relevant option rights are exercised).

(5) Consists of (a) 589,387 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 (a) 1,652,040 ordinary shares held by CHuber 2008 GmbH and (b) 960,979 ordinary shares held by immediate family members of Mr. Huber. Mr. Huber is the majority shareholder of CHuber 2008 GmbH. Mr. Huber disclaims beneficial ownership of the 960,979 ordinary shares held by immediate family members except to the extent of his pecuniary interest therein.

(8) Consists of 1,480 ordinary shares held by beebusy Capital GmbH. Ulrich Wandschneider is sole shareholder of beebusy Capital GmbH.

(9) Consists of (a) 200 ordinary shares held directly by Anja Morawietz and (b) 40 ordinary shares held by immediate family members of Anja Morawietz.

(10) 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

Agreements with Santo Service GmbH

Until December 31, 2022, we had several agreements with Santo Service GmbH, or Santo Service, pursuant to which Santo Service provided us with certain real property and custodial services. Santo Service is wholly owned by AT Impf GmbH, one of our major shareholders. During the year ended December 31, 2022, the aggregate value of transactions with Santo Service amounted to €62.8 million pursuant to these agreements (€0.9 million during the year ended December 31, 2021). 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.

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.
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 Fiscal Years

Our share capital as registered with the commercial register (Handelsregister) amounts to €248,552,200, including an amount of €5,337,031 relating to 5,337,031 ordinary shares held in treasury as of December 31, 2022. Since January 1, 2020, our share capital has changed as follows:

- On April 23, 2020, our share capital as registered with the commercial register (Handelsregister) was increased by issuing 1,580,777 shares;
- On May 5, 2020, our share capital as registered with the commercial register (Handelsregister) was increased by issuing 2,377,446 shares;
• On May 8, 2020, our share capital as registered with the commercial register (Handelsregister) was increased by issuing 1,935,488 shares;

• On July 24, 2020, our share capital as registered with the commercial register (Handelsregister) was increased by issuing 5,500,000 shares;

• On August 24, 2020, our share capital as registered with the commercial register (Handelsregister) was increased by issuing 16,124 shares;

• On September 8, 2020, our share capital as registered with the commercial register (Handelsregister) was increased by issuing 2,595,996 shares;

• 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 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 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 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 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 (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 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 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 36 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 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 consolidated 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” (ausreichende Minderheitsabkömmnisse). 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, Belarus, Burundi, D.R. Congo, Central African Republic, China, Guinea, Guinea-Bissau, Haiti, Iran, Iraq, Lebanon, Libya, Mali, Myanmar, Nicaragua, North Korea, Russia, Somalia, South Sudan, Sudan, Syria, Tanzania, Turkey, 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.

199
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-S220412/10003, as amended by the circular dated December 18, 2018 (reference number IV C 1 – S 220412/10003), 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 Depositary 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 when the circumstances described in the preceding paragraph and therefore should not be subject to German taxation on capital gains from the disposal 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 of 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 custodial 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 prior to and ending 45 days within a period starting 45 days before 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.
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 underlyng 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 depositary of the shares upon request of the foreign depositary 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 ADSs 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 (Geschäftsleitstelle) 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).

#### ADS 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) or a 5.5% solidarity surcharge (Solidaritätszuschlag) thereon, resulting in an aggregate rate of 30.575%, 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.

#### ADS as Business Assets (Betriebsvermögen)

If the ADSs are held as business assets by a German tax resident, dividends and capital gains (other than capital gains from the disposition of a Qualifying Participation) are taxed as business income (Betriebsvermögen) of the German company that owns the ADSs and are subject to 15% flat income tax and the solidarity surcharge. The flat income tax rate may be subjected to a 50% reduction if the shareholder holds a 10% or more ownership interest in the company that owns the ADSs. Further, such income is also subject to a 15% flat rate on capital gains realized from the disposition of ADSs.

In general, the deduction of expenses related to the investment income (including dividends or gains with respect to ADSs) is generally not possible for private investors.

203
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 (Mitunternehmerschaften), 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 (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, subject to the limitations described above in “—ADSs as Private Assets (Privatvermögen)”.

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 his 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.

205
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 depositary 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 includable 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 includable 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 do not believe that we should be treated as PFIC for our 2022 taxable year. Because the determination of our PFIC status is made annually based on the factual tests described below, however, we cannot provide any assurances regarding our PFIC status for the current or 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, which may fluctuate considerably. 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.

If we were classified as a PFIC in any taxable year, a U.S. Holder would be subject to special rules with respect to distributions on and sales, exchanges and other dispositions of the ADSs. We will be 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. However, 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 were 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 would 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 will be treated as ordinary income and will be 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 would be subject to tax at the U.S. Holder’s regular ordinary income rate for the current year and would not be 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 were determined to be a PFIC, this tax treatment for U.S. Holders would apply 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 would not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under “—Taxation of Dividends.”

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 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 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 would alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment of the ADSs, as described below.

If we were a PFIC, the rules above would not apply to a U.S. Holder that makes an election to treat ADSs as stock of a “qualified electing fund” or QEF. However, we do not expect that a U.S. Holder would be able to make this election because we do not intend to provide to U.S. Holders the required information to make a valid QEF election.

If we were a PFIC, the rules above also would not apply to a U.S. Holder that makes a “mark-to-market” election with respect to the ADSs, but this election will be 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 of ADSs will be 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 were 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 would apply to any mark-to-market gain recognized in the year the election is made.

208
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). The failure to file IRS Form 8621 could result in the imposition of penalties and the extension of the statute of limitations with respect to U.S. federal income tax.

U.S. Holders are urged to consult their tax advisors as to their 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 common stock 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 which significantly increased in the past year. Since December 2020, our COVID-19 vaccine has been fully approved, granted conditional marketing authorization, or approved or authorized for emergency or temporary use, which resulted in recognition of revenues from the commercial sale of pharmaceutical products for the first time. Consequently, we have progressed from earning revenues primarily from research and development to earning revenues from commercial sales. 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 as well as expanding our global footprint further. Especially when funds are required in Euros, we are exposed to foreign currency exchange risks. With the aim of preserving capital, surplus liquidity is invested carefully for example into foreign currency investments. 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, a matter of principle, foreign exchange forward contracts are concluded 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
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, 2022 would have an effect of €215.7 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

<table>
<thead>
<tr>
<th>Persons depositing or withdrawing shares or ADS holders must pay:</th>
<th>For:</th>
</tr>
</thead>
<tbody>
<tr>
<td>$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)</td>
<td>Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property</td>
</tr>
<tr>
<td>$0.05 (or less) per ADS</td>
<td>Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates</td>
</tr>
<tr>
<td>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</td>
<td>Any cash distribution to ADS holders</td>
</tr>
<tr>
<td>$0.05 (or less) per ADS per calendar year</td>
<td>Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders</td>
</tr>
<tr>
<td>Registration or transfer fees</td>
<td>Depositary services</td>
</tr>
<tr>
<td>Expenses of the depositary</td>
<td>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</td>
</tr>
<tr>
<td>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</td>
<td>Cable and facsimile transmissions (when expressly provided in the deposit agreement)</td>
</tr>
<tr>
<td>Any charges incurred by the depositary or its agents for servicing the deposited securities</td>
<td>Converting foreign currency to U.S. dollars</td>
</tr>
</tbody>
</table>

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.

212
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 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 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, 2022. 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, 2022 is effective.

Attestation Report of the Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2022 has been audited by Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, an independent registered public accounting firm. Their report is included on page F-2. Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft is a member of the Chamber of Public Accountants (Wirtschaftsprüferkammer), Berlin, Germany.

Changes in Control over Financial Reporting

There were no changes to our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Securities and Exchange Act of 1934) that occurred during the period covered by this form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16. [Reserved]

Item 16A. Audit Committee Financial Expert

Our Audit Committee for the year ended December 31, 2022 consisted of Ulrich Wandschneider, Ph.D. (Chair), Prof. Christoph Huber, M.D. and Michael Motschmann. As of January 1, 2023, our Audit Committee comprises Anja Morawietz (Chair), Ulrich Wandschneider, Ph.D. and Prof. Rudolf Staudigl, Ph.D. 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

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, or EY, has served as our independent registered public accounting firm for the years ended December 31, 2022, December 31, 2021, December 31, 2020 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:

<table>
<thead>
<tr>
<th></th>
<th>Years ended December 31, 2022</th>
<th>Years ended December 31, 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(in millions)</td>
<td>(in millions)</td>
</tr>
<tr>
<td>Audit fees</td>
<td>€2.9</td>
<td>€1.9</td>
</tr>
<tr>
<td>Audit-related fees</td>
<td>0.4</td>
<td>0.7</td>
</tr>
<tr>
<td>Tax fees</td>
<td>0.2</td>
<td>0.5</td>
</tr>
<tr>
<td>All other fees</td>
<td>0.2</td>
<td>0.1</td>
</tr>
<tr>
<td><strong>Total fees for professional audit services and other services</strong></td>
<td><strong>€3.7</strong></td>
<td><strong>€3.2</strong></td>
</tr>
</tbody>
</table>

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, 2021, audit fees related to the integrated audit of our consolidated financial statements as set out in this Annual Report and our internal control over financial reporting as well as professional services related to our statutory and regulatory filings for our subsidiaries.

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, 2021, audit-related fees were attributable to assurance and related services including attest related services, accounting consultation as well as services for our at-the-market offering program.

In the year ended December 31, 2022, tax service fees were billed for services in conjunction with transactions, especially with our financing and deal transactions. In the year ended December 31, 2021, tax service fees billed for services in conjunction with transactions, especially with our financing and deal transactions.

In the year ended December 31, 2022, other fees were comprised of fees for services for grant applications and consultancy services around management compensation. In the year ended December 31, 2021, other fees were comprised of fees for services for grant applications for our COVID-19 vaccine program and accounting assessments of different accounting topics.

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, 2022 and 2021 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 in 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 a share repurchase program of ADSs, pursuant to which we may repurchase ADSs in the amount of up to $1.5 billion over the next two years, which was announced on March 31, 2022. On May 2, 2022, the first tranche of our share repurchase program of ADSs, with a value of up to $1.0 billion, commenced. In November 2022, our Management Board and Supervisory Board authorized the second tranche of our share repurchase program of ADSs, with a value of up to $0.5 billion, commencing on December 7, 2022. During the year ended December 31, 2022, ADSs were purchased at an average price of $143.98, for total consideration of $1.0 billion (€986.4 million). Repurchased ADSs were used to satisfy settlement obligations under our share-based payment arrangements.

215
## First Tranche ($1.0 billion)

<table>
<thead>
<tr>
<th>Period</th>
<th>Number of ADSs purchased</th>
<th>Average price paid per ADS</th>
<th>Total number of ADSs purchased</th>
<th>Approximate value of ADSs that may yet be purchased (in millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 2022(1)</td>
<td>917,988</td>
<td>$151.76 (€143.99)</td>
<td>917,988</td>
<td>$860.7 (€867.8)</td>
</tr>
<tr>
<td>June 2022</td>
<td>1,160,219</td>
<td>$140.82 (€133.35)</td>
<td>2,078,207</td>
<td>697.3 (€713.1)</td>
</tr>
<tr>
<td>July 2022</td>
<td>519,320</td>
<td>$162.03 (€159.40)</td>
<td>2,597,527</td>
<td>613.2 (€630.3)</td>
</tr>
<tr>
<td>August 2022</td>
<td>1,666,515</td>
<td>$149.08 (€148.24)</td>
<td>4,264,042</td>
<td>364.8 (€383.3)</td>
</tr>
<tr>
<td>September 2022</td>
<td>2,280,988</td>
<td>$135.95 (€137.66)</td>
<td>6,545,030</td>
<td>54.6 (€60.3)</td>
</tr>
<tr>
<td>October 2022</td>
<td>400,483</td>
<td>$136.37 (€139.09)</td>
<td>6,995,513</td>
<td>— (€13.6)</td>
</tr>
<tr>
<td>Total</td>
<td>6,945,513</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(1) Beginning May 2, 2022.
(2) Beginning December 7, 2022.
(3) Ending March 17, 2023.

All purchases disclosed in this table above were purchased under Rule 10b5-1 trading plans pursuant to such share repurchase program. The trading plan for the second tranche of our share repurchase program expired on March 17, 2023.

In total 9,166,684 ADSs were repurchased at an average price of $142.04, for total consideration of approximately $1.3 billion (€1,268.4 million).

## Second Tranche ($0.5 billion)

<table>
<thead>
<tr>
<th>Period</th>
<th>Number of ADSs purchased</th>
<th>Average price paid per ADS</th>
<th>Total number of ADSs purchased</th>
<th>Approximate value of ADSs that may yet be purchased (in millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2022</td>
<td>618,355</td>
<td>$142.26 (€131.12)</td>
<td>618,355</td>
<td>412.0 (€418.9)</td>
</tr>
<tr>
<td>January 2023</td>
<td>857,620</td>
<td>$138.05 (€129.06)</td>
<td>1,475,975</td>
<td>293.6 (€308.2)</td>
</tr>
<tr>
<td>March 2023(3)</td>
<td>745,196</td>
<td>$128.49 (€121.08)</td>
<td>2,221,171</td>
<td>197.9 (€218.0)</td>
</tr>
<tr>
<td>Total</td>
<td>2,211,171</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(1) Beginning May 2, 2022.
(2) Beginning December 7, 2022.
(3) Ending March 17, 2023.

New Share Repurchase Program 2023

We expect our Management Board and Supervisory Board to authorize a share repurchase program of ADSs, pursuant to which we may repurchase ADSs in the amount of up to $0.5 billion during the year 2023. We expect to use all or a portion of the ADSs we repurchase and hold in treasury to satisfy upcoming settlement obligations under our share-based payment arrangements.

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.

<table>
<thead>
<tr>
<th>European Union/Federal Republic of Germany</th>
<th>Delaware</th>
</tr>
</thead>
<tbody>
<tr>
<td>Board System</td>
<td>Board System</td>
</tr>
<tr>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>The Management Board is responsible for running the company’s affairs and representing the company in dealings with third parties.</td>
<td>Management is responsible for running the corporation and overseeing its day-to-day operations.</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>
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 (große 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, 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.
<table>
<thead>
<tr>
<th>Table of Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vacancies on the Board of Directors</td>
</tr>
<tr>
<td>Annual General Meeting</td>
</tr>
<tr>
<td>General Meeting</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
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.

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, 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.

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 | 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. |
| 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. |
| Authority to Allot | 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>
<table>
<thead>
<tr>
<th>Table of Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Liability of Directors and Officers</strong></td>
</tr>
</tbody>
</table>
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.

| **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.

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.

Under Delaware law, a corporation’s certificate of incorporation may include a provision eliminating or limiting the personal liability of a director.

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.

223
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.
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. 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.

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.
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) needs(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) 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 16. Mine Safety Disclosure

Not applicable.

Item 16. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

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.
<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1*</td>
<td>Articles of Association of the Registrant</td>
</tr>
<tr>
<td>2.1</td>
<td>Form of Specimen American Depositary Receipt (included in Exhibit 2.3)</td>
</tr>
<tr>
<td>2.2</td>
<td>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. 333-233888), filed with the SEC on September 9, 2019)</td>
</tr>
<tr>
<td>2.3</td>
<td>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)</td>
</tr>
<tr>
<td>2.4*</td>
<td>Description of Securities of the Registrant</td>
</tr>
<tr>
<td>4.2†</td>
<td>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. 333-233888), filed with the SEC on September 9, 2019)</td>
</tr>
<tr>
<td>4.4†</td>
<td>License Agreement by and among the Registrant, TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, Johannes Gutenberg-Universität und Universitätsmedizin der Johannes Gutenberg Universität Mainz, and Gampel 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. 333-233888), filed with the SEC on September 9, 2019)</td>
</tr>
<tr>
<td>4.6†</td>
<td>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. 333-233888), filed with the SEC on September 9, 2019)</td>
</tr>
</tbody>
</table>
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)

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)

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)

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 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, 2020)

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, 2020)

Second Amendment to Patent Sublicense Agreement by and between mRNA RiboTherapeutics, Inc. and BioNTech RNA Pharmaceuticals GmbH, dated July 14, 2017 (incorporated herein by reference to Exhibit 4.4 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)

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 4.19 to the Registrant’s Annual Report on Form 20-F (File No. 001-39081), filed with the SEC on September 9, 2019)

Second Amendment to Patent Sublicense Agreement by and between mRNA RiboTherapeutics, Inc. and BioNTech RNA Pharmaceuticals GmbH, dated July 14, 2017 (incorporated herein by reference to Exhibit 4.4 to the Registrant’s Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)

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) |
| 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, 2014 (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† Sales Agreement by and among the Registrant, Jefferies LLC and SVB Leerink LLC, dated November 9, 2020 (incorporated herein by reference to Exhibit 1.2 to the Registrant’s Registration Statement on Form F-3 (File No. 333-249991), filed with the SEC on November 10, 2020)

4.31† 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 1.13 to the Registrant’s Registration Statement on Form F-3 (File No. 333-249991), filed with the SEC on November 10, 2020)

4.32† Purchase Agreement by and among BioNTech Manufacturing GmbH, Pfizer Inc., and the European Commission, dated February 17, 2021 (incorporated herein by reference to Exhibit 1.14 to the Registrant’s Registration Statement on Form F-3 (File No. 333-249991), filed with the SEC on March 30, 2021)

4.33† 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)

4.34† 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

4.35† 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

4.36† 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

4.37† License Agreement by and between the Registrant and Acuitas Therapeutics, Inc., dated as of April 7, 2020

4.38† Advanced Purchase Agreement by and among the Registrant, Pfizer Inc. and European Commission, dated as of May 20, 2021
Transfer of Source Code for MyMUT Software Versions by and between the Registrant and TRON gGmbH, dated as of May 5, 2021

Amendment No. 6 to Lease Agreement by and between the Registrant and Tech Park 270, LLC, dated as of August 2, 2021

Side Letter No. 5 to License and Collaboration Agreement by and between Registrant and Genmab A/S, dated August 12, 2021

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

Transfer of Source Code MyMUT Software Versions by and between the Registrant and TRON gGmbH, dated as of September 10, 2021

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

Lease for Areas and Rooms in Building 536 and 537 by and between the Pharmaserv GmbH and Novartis Manufacturing GmbH, dated on January 29, 2022

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

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

Agreement relating 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 January 10, 2023

List of Subsidiaries of the Registrant

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

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

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

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

Consent of Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

Inline XBRL Instance Document

Inline XBRL Taxonomy Extension Schema Document

Inline XBRL Taxonomy Extension Calculation Linkbase Document

Inline XBRL Taxonomy Extension Definition Linkbase Document

Inline XBRL Taxonomy Extension Label Linkbase Document

Inline XBRL Taxonomy Extension Presentation Linkbase Document

Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

Filed herewith.
† Certain information has been excluded from the exhibit because it is both (i) not material and (ii) the type that the Registrant treats as private or confidential.
The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this Annual Report on Form 20-F on its behalf.

BioNTech SE

Date: March 27, 2023

By: /s/ Prof. Ugur Sahin, M.D.

Prof. Ugur Sahin, M.D.
Chief Executive Officer
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Reports of Independent Registered Public Accounting Firm (PCAOB ID: 01251) ........................................... F-2
Consolidated Statements of Profit or Loss for the Years ended December 31, 2022, 2021 and 2020 .................. F-5
Consolidated Statements of Financial Position as of December 31, 2022 and 2021 ........................................ F-7
Consolidated Statements of Changes in Stockholders’ Equity for the Years ended December 31, 2022, 2021 and 2020 ................................................................. F-8
Consolidated Statements of Cash Flows for the Years ended December 31, 2022, 2021 and 2020 ............... F-9
Notes to Consolidated Financial Statements ................................................................................................ F-10
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Supervisory Board 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, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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 27, 2023 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.

F-2
Revenue recognition from collaboration partner's COVID-19 vaccine sales

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 €17.1 billion. This includes €12.5 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

As described in more detail in Note 17 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 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.
Opinion on Internal Control Over Financial Reporting

We have audited BioNTech SE’s internal control over financial reporting as of December 31, 2022, 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, 2022, based on the COSO criteria.

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, 2022 and 2021, 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, 2022, and the related notes and our report dated March 27, 2023 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.

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/ Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft
Cologne, Germany
March 27, 2023
## Consolidated Statements of Profit or Loss

<table>
<thead>
<tr>
<th>Note</th>
<th>2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Revenues</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Commercial revenues</td>
<td>€17,194.6</td>
<td>€18,874.0</td>
</tr>
<tr>
<td></td>
<td>Research &amp; development revenues</td>
<td>6</td>
<td>116.0</td>
</tr>
<tr>
<td></td>
<td>Total revenues</td>
<td>€17,310.6</td>
<td>€18,976.7</td>
</tr>
<tr>
<td></td>
<td>Cost of sales</td>
<td>7.1</td>
<td>(2,995.0)</td>
</tr>
<tr>
<td></td>
<td>Research and development expenses</td>
<td>7.2</td>
<td>(1,537.0)</td>
</tr>
<tr>
<td></td>
<td>Sales and marketing expenses</td>
<td>7.3</td>
<td>(59.5)</td>
</tr>
<tr>
<td></td>
<td>General and administrative expenses</td>
<td>7.4</td>
<td>(484.7)</td>
</tr>
<tr>
<td></td>
<td>Other operating expenses</td>
<td>7.5</td>
<td>(407.0)</td>
</tr>
<tr>
<td></td>
<td>Other operating income</td>
<td>7.6</td>
<td>815.5</td>
</tr>
<tr>
<td></td>
<td>Operating income / (loss)</td>
<td>7.7</td>
<td>€11,265.7</td>
</tr>
<tr>
<td></td>
<td>Finance income</td>
<td>7.7</td>
<td>339.3</td>
</tr>
<tr>
<td></td>
<td>Finance expenses</td>
<td>7.8</td>
<td>(18.9)</td>
</tr>
<tr>
<td></td>
<td>Profit / (loss) before tax</td>
<td>7.8</td>
<td>€11,964.4</td>
</tr>
<tr>
<td></td>
<td>Income taxes</td>
<td>8</td>
<td>(3,519.7)</td>
</tr>
<tr>
<td></td>
<td>Profit for the period</td>
<td>7.8</td>
<td>€8,444.4</td>
</tr>
<tr>
<td></td>
<td>Earnings per share</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Basic profit for the period per share</td>
<td>€38.78</td>
<td>€42.18</td>
</tr>
<tr>
<td></td>
<td>Diluted profit for the period per share</td>
<td>€37.77</td>
<td>€39.63</td>
</tr>
</tbody>
</table>

The accompanying notes form an integral part of these consolidated financial statements.

F-5
## Consolidated Statements of Comprehensive Income

<table>
<thead>
<tr>
<th></th>
<th>Note</th>
<th>2022 (in millions)</th>
<th>2021 (in millions)</th>
<th>2020 (in millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Profit for the period</strong></td>
<td></td>
<td>€9,434.4</td>
<td>€10,292.5</td>
<td>€15.2</td>
</tr>
<tr>
<td><strong>Other comprehensive income</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other comprehensive income that may be reclassified to profit or loss in subsequent periods, net of tax</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exchange differences on translation of foreign operations</td>
<td></td>
<td>€11.2</td>
<td>€8.4</td>
<td>(€11.1)</td>
</tr>
<tr>
<td><strong>Net other comprehensive income / (loss) that may be reclassified to profit or loss in subsequent periods</strong></td>
<td></td>
<td>€11.2</td>
<td>€8.4</td>
<td>(€11.1)</td>
</tr>
<tr>
<td>Other comprehensive loss that will not be reclassified to profit or loss in subsequent periods, net of tax</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net gain on equity instruments designated at fair value through other comprehensive income</td>
<td></td>
<td>€10.5</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Remeasurement income / (loss) on defined benefit plans</td>
<td></td>
<td>0.6</td>
<td>0.3</td>
<td>(0.3)</td>
</tr>
<tr>
<td><strong>Net other comprehensive income / (loss) that will not be reclassified to profit or loss in subsequent periods</strong></td>
<td></td>
<td>€11.1</td>
<td>€0.3</td>
<td>(€0.3)</td>
</tr>
<tr>
<td><strong>Other comprehensive income / (loss) for the period, net of tax</strong></td>
<td></td>
<td>€22.3</td>
<td>€8.7</td>
<td>(€11.4)</td>
</tr>
<tr>
<td><strong>Comprehensive income for the period, net of tax</strong></td>
<td></td>
<td>€9,456.7</td>
<td>€10,301.2</td>
<td>€3.8</td>
</tr>
</tbody>
</table>

The accompanying notes form an integral part of these consolidated financial statements.
<table>
<thead>
<tr>
<th>Section</th>
<th>December 31, 2022</th>
<th>December 31, 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Non-current assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intangible assets</td>
<td>€ 219.7</td>
<td>€ 202.4</td>
</tr>
<tr>
<td>Property, plant and equipment</td>
<td>€ 609.2</td>
<td>€ 322.5</td>
</tr>
<tr>
<td>Right-of-use assets</td>
<td>€ 211.9</td>
<td>€ 197.9</td>
</tr>
<tr>
<td>Other financial assets</td>
<td>€ 80.2</td>
<td>€ 21.3</td>
</tr>
<tr>
<td>Other non-financial assets</td>
<td>€ 6.5</td>
<td>€ 14.4</td>
</tr>
<tr>
<td>Deferred tax assets</td>
<td>€ 229.6</td>
<td></td>
</tr>
<tr>
<td><strong>Total non-current assets</strong></td>
<td>€ 1,357.1</td>
<td>€ 758.5</td>
</tr>
<tr>
<td><strong>Current assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inventories</td>
<td>€ 439.6</td>
<td>€ 502.5</td>
</tr>
<tr>
<td>Trade and other receivables</td>
<td>€ 7,145.6</td>
<td>€ 12,381.7</td>
</tr>
<tr>
<td>Other financial assets</td>
<td>€ 189.4</td>
<td>€ 381.6</td>
</tr>
<tr>
<td>Other non-financial assets</td>
<td>€ 271.9</td>
<td>€ 113.4</td>
</tr>
<tr>
<td>Income tax assets</td>
<td>€ 0.4</td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>€ 13,875.1</td>
<td>€ 1,692.7</td>
</tr>
<tr>
<td><strong>Total current assets</strong></td>
<td>€ 21,922.0</td>
<td>€ 15,072.3</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td>€ 23,279.1</td>
<td>€ 15,830.8</td>
</tr>
<tr>
<td><strong>Equity and liabilities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Equity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Share capital</td>
<td>€ 248.6</td>
<td>€ 246.3</td>
</tr>
<tr>
<td>Capital reserve</td>
<td>€ 1,828.2</td>
<td>€ 1,674.4</td>
</tr>
<tr>
<td>Treasury shares</td>
<td>€ (5.3)</td>
<td>€ (3.8)</td>
</tr>
<tr>
<td>Retained earnings</td>
<td>€ 18,333.0</td>
<td>€ 9,382.9</td>
</tr>
<tr>
<td>Other reserves</td>
<td>€ (848.9)</td>
<td>€ 93.9</td>
</tr>
<tr>
<td><strong>Total equity</strong></td>
<td>€ 20,055.6</td>
<td>€ 11,893.7</td>
</tr>
<tr>
<td><strong>Non-current liabilities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lease liabilities, loans and borrowings</td>
<td>€ 176.2</td>
<td>€ 171.6</td>
</tr>
<tr>
<td>Other financial liabilities</td>
<td>€ 6.1</td>
<td>€ 6.1</td>
</tr>
<tr>
<td>Income tax liabilities</td>
<td>€ 10.4</td>
<td>€ 4.4</td>
</tr>
<tr>
<td>Provisions</td>
<td>€ 8.6</td>
<td>€ 184.9</td>
</tr>
<tr>
<td>Contract liabilities</td>
<td>€ 48.4</td>
<td>€ 9.0</td>
</tr>
<tr>
<td>Other non-financial liabilities</td>
<td>€ 17.0</td>
<td>€ 12.8</td>
</tr>
<tr>
<td>Deferred tax liabilities</td>
<td>€ 6.2</td>
<td>€ 66.7</td>
</tr>
<tr>
<td><strong>Total non-current liabilities</strong></td>
<td>€ 272.9</td>
<td>€ 455.5</td>
</tr>
<tr>
<td><strong>Current liabilities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lease liabilities, loans and borrowings</td>
<td>€ 36.0</td>
<td>€ 129.9</td>
</tr>
<tr>
<td>Trade payables</td>
<td>€ 204.1</td>
<td>€ 160.0</td>
</tr>
<tr>
<td>Other financial liabilities</td>
<td>€ 785.1</td>
<td>€ 1,190.4</td>
</tr>
<tr>
<td>Refund liabilities</td>
<td>€ 24.4</td>
<td>€ 90.0</td>
</tr>
<tr>
<td>Income tax liabilities</td>
<td>€ 595.9</td>
<td>€ 1,568.9</td>
</tr>
<tr>
<td>Provisions</td>
<td>€ 367.2</td>
<td>€ 110.2</td>
</tr>
<tr>
<td>Contract liabilities</td>
<td>€ 77.1</td>
<td>€ 186.1</td>
</tr>
<tr>
<td>Other non-financial liabilities</td>
<td>€ 96.8</td>
<td>€ 46.1</td>
</tr>
<tr>
<td><strong>Total current liabilities</strong></td>
<td>€ 2,950.6</td>
<td>€ 3,481.6</td>
</tr>
<tr>
<td><strong>Total liabilities</strong></td>
<td>€ 3,223.5</td>
<td>€ 3,937.1</td>
</tr>
<tr>
<td><strong>Total equity and liabilities</strong></td>
<td>€ 23,279.1</td>
<td>€ 15,830.8</td>
</tr>
</tbody>
</table>

The accompanying notes form an integral part of these consolidated financial statements.

F-7
<table>
<thead>
<tr>
<th>Note</th>
<th>Share capital</th>
<th>Capital reserve</th>
<th>Treasury shares</th>
<th>Retained earnings</th>
<th>Other reserves</th>
<th>Total equity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(in millions)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>As of January 1, 2020</td>
<td>€ 232.3</td>
<td>€ 686.7</td>
<td>(5.5)</td>
<td>€ (424.8)</td>
<td>€ 4.8</td>
<td>€ 493.5</td>
</tr>
<tr>
<td>Profit for the period</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>€ 15.2</td>
<td></td>
</tr>
<tr>
<td>Other comprehensive loss</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total comprehensive profit / (loss)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>€ 15.2</td>
<td>(11.4) € 3.8</td>
</tr>
<tr>
<td>Issuance of share capital</td>
<td></td>
<td>14.0</td>
<td>861.0</td>
<td>0.7</td>
<td></td>
<td>€ 875.7</td>
</tr>
<tr>
<td>Transaction costs</td>
<td></td>
<td></td>
<td></td>
<td>(33.2)</td>
<td></td>
<td>€ (33.2)</td>
</tr>
<tr>
<td>Share-based payments</td>
<td>17</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>€ 32.0</td>
</tr>
<tr>
<td>As of December 31, 2020</td>
<td>€ 246.3</td>
<td>€ 1,514.5</td>
<td>(4.8)</td>
<td>€ (409.6)</td>
<td>€ 25.4</td>
<td>€ 1,371.8</td>
</tr>
<tr>
<td>Profit for the period</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10,292.5</td>
<td>€ 10,292.5</td>
</tr>
<tr>
<td>Other comprehensive income</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total comprehensive income</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>€ 8.7</td>
<td>€ 8.7</td>
</tr>
<tr>
<td>Issuance of treasury shares</td>
<td>16</td>
<td></td>
<td>162.5</td>
<td>1.0</td>
<td></td>
<td>€ 163.6</td>
</tr>
<tr>
<td>Transaction costs</td>
<td></td>
<td></td>
<td></td>
<td>(2.7)</td>
<td></td>
<td>€ (2.7)</td>
</tr>
<tr>
<td>Share-based payments</td>
<td>17</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>€ 59.8</td>
</tr>
<tr>
<td>As of December 31, 2021</td>
<td>€ 246.3</td>
<td>€ 1,674.4</td>
<td>(3.8)</td>
<td>€ 9,882.9</td>
<td>€ 93.9</td>
<td>€ 11,893.7</td>
</tr>
<tr>
<td>Profit for the period</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>9,434.4</td>
<td>€ 9,434.4</td>
</tr>
<tr>
<td>Other comprehensive income</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total comprehensive income</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>€ 22.3</td>
<td>€ 22.3</td>
</tr>
<tr>
<td>Issuance of share capital</td>
<td>15</td>
<td></td>
<td>0.5</td>
<td>67.1</td>
<td></td>
<td>€ 67.6</td>
</tr>
<tr>
<td>Redemption of convertible note</td>
<td>12</td>
<td></td>
<td>1.8</td>
<td>233.2</td>
<td></td>
<td>€ 235.0</td>
</tr>
<tr>
<td>Share repurchase program</td>
<td>15</td>
<td></td>
<td>(979.5)</td>
<td>(6.9)</td>
<td></td>
<td>€ (986.4)</td>
</tr>
<tr>
<td>Transaction costs</td>
<td></td>
<td></td>
<td></td>
<td>(0.1)</td>
<td></td>
<td>€ (0.1)</td>
</tr>
<tr>
<td>Dividends</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>€ (484.3)</td>
</tr>
<tr>
<td>Share-based payments</td>
<td>16</td>
<td></td>
<td>833.1</td>
<td>5.4</td>
<td>(1,519.8)</td>
<td>€ (681.3)</td>
</tr>
<tr>
<td>Current and deferred taxes</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td>554.7</td>
<td>€ 554.7</td>
</tr>
<tr>
<td>As of December 31, 2022</td>
<td>€ 248.6</td>
<td>€ 1,828.2</td>
<td>(5.3)</td>
<td>€ 18,833.0</td>
<td>€ (848.9)</td>
<td>€ 20,055.6</td>
</tr>
</tbody>
</table>

(1) Includes foreign currency translation reserve which was presented separately in prior periods.
## Consolidated Statements of Cash Flows

<table>
<thead>
<tr>
<th>Year ended</th>
<th>2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operating activities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Profit for the period</td>
<td>€ 9,434.4</td>
<td>€ 10,292.5</td>
<td>€ 15,258.1</td>
</tr>
<tr>
<td>Income taxes</td>
<td>3,519.7</td>
<td>4,753.9</td>
<td>(161.0)</td>
</tr>
<tr>
<td><strong>Profit before tax</strong></td>
<td>€12,954.1</td>
<td>€15,046.4</td>
<td>€145.8</td>
</tr>
<tr>
<td>Adjustments to reconcile profit before tax to net cash flows:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation and amortization of property, plant, equipment, intangible assets and right-of-use assets</td>
<td>123.3</td>
<td>75.2</td>
<td>38.7</td>
</tr>
<tr>
<td>Share-based payment expenses</td>
<td>108.6</td>
<td>93.9</td>
<td>32.1</td>
</tr>
<tr>
<td>Net foreign exchange differences</td>
<td>625.5</td>
<td>(387.5)</td>
<td>41.3</td>
</tr>
<tr>
<td>Loss on disposal of property, plant and equipment</td>
<td>0.6</td>
<td>4.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Finance income excluding foreign exchange differences</td>
<td>(265.3)</td>
<td>(1.7)</td>
<td>(1.6)</td>
</tr>
<tr>
<td>Finance expense excluding foreign exchange differences</td>
<td>18.9</td>
<td>305.2</td>
<td>22.3</td>
</tr>
<tr>
<td>Movements in government grants</td>
<td>0.3</td>
<td>(89.0)</td>
<td>92.0</td>
</tr>
<tr>
<td>Other non-cash income / (loss)</td>
<td>—</td>
<td>(2.2)</td>
<td>1.7</td>
</tr>
<tr>
<td>Unrealized net (gain) / loss on derivative instruments at fair value through profit or loss</td>
<td>(241.0)</td>
<td>57.3</td>
<td>—</td>
</tr>
<tr>
<td><strong>Working capital adjustments:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decrease / (increase) in trade and other receivables, contract assets and other assets</td>
<td>4,369.9</td>
<td>(11,808.1)</td>
<td>(247.9)</td>
</tr>
<tr>
<td>Decrease / (increase) in inventories</td>
<td>62.9</td>
<td>(438.4)</td>
<td>(49.8)</td>
</tr>
<tr>
<td><strong>Net cash flows from / (used in) operating activities</strong></td>
<td>€13,577.4</td>
<td>€889.7</td>
<td>€(13.5)</td>
</tr>
<tr>
<td><strong>Investing activities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchase of property, plant and equipment</td>
<td>(329.2)</td>
<td>(127.5)</td>
<td>(66.0)</td>
</tr>
<tr>
<td>Proceeds from sale of property, plant and equipment</td>
<td>0.6</td>
<td>3.4</td>
<td>1.2</td>
</tr>
<tr>
<td>Purchase of intangible assets and right-of-use assets</td>
<td>(34.1)</td>
<td>(26.5)</td>
<td>(19.4)</td>
</tr>
<tr>
<td>Acquisition of subsidiaries and businesses, net of cash acquired</td>
<td>(20.8)</td>
<td>(60.6)</td>
<td>—</td>
</tr>
<tr>
<td>Purchase of financial instruments</td>
<td>(47.8)</td>
<td>(19.5)</td>
<td>—</td>
</tr>
<tr>
<td><strong>Net cash flows used in investing activities</strong></td>
<td>€(353.5)</td>
<td>€(566.5)</td>
<td>€(144.8)</td>
</tr>
<tr>
<td><strong>Financing activities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proceeds from issuance of share capital and treasury shares, net of costs</td>
<td>110.5</td>
<td>160.9</td>
<td>753.0</td>
</tr>
<tr>
<td>Proceeds from loans and borrowings</td>
<td>0.8</td>
<td>156.0</td>
<td>—</td>
</tr>
<tr>
<td>Repayment of loans and borrowings</td>
<td>(18.8)</td>
<td>(52.6)</td>
<td>(1.6)</td>
</tr>
<tr>
<td>Payments related to lease liabilities</td>
<td>(41.1)</td>
<td>(14.1)</td>
<td>(12.7)</td>
</tr>
<tr>
<td>Share repurchase program</td>
<td>(986.4)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Dividends</td>
<td>(484.3)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Net cash flows from / (used in) financing activities</strong></td>
<td>€(1,419.3)</td>
<td>€942.2</td>
<td>€894.7</td>
</tr>
<tr>
<td><strong>Net increase in cash and cash equivalents</strong></td>
<td>€13,875.1</td>
<td>€1,692.7</td>
<td>€1,210.2</td>
</tr>
<tr>
<td><strong>Cash and cash equivalents at December 31</strong></td>
<td>€13,875.1</td>
<td>€1,692.7</td>
<td>€1,210.2</td>
</tr>
</tbody>
</table>

The accompanying notes form an integral part of these 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 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 45720. The accompanying International Financial Reporting Standards (IFRS) consolidated financial statements present the financial position and the results of operation 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, 2022, were authorized for issue in accordance with a resolution of the Supervisory Board on March 26, 2023.

2 Significant Accounting Policies

2.1 Basis of Preparation

General

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Financial Reporting 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.

F-10
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 Significant Accounting Policies

2.3.1 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 2.3.14. 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 disposed operation is included in the carrying amount of the operation when determining the gain or loss on disposal. Goodwill disposed in these circumstances is measured based on the relative values of the disposed operation and the portion of the cash-generating unit retained.

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 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.

2.3.4 Revenue from Contracts with Customers

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 judgement 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.

Earnings 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, or as, the underlying sales occur, which is when the performance obligation has been satisfied. As described further in Note 3 certain judgment is applied 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, are accounted for as gross revenues. Any consideration related to activities in which we are considered the agent, are 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 fiscal 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).

F-13
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.

2.3.5 Government Grants

Government grants 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, associates and interests in joint arrangements, 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, associates and interests in joint arrangements, 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 (so-called Pillar 2). The Global Anti-Bas Erosion Rules shall ensure 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 so-called OECD 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 EU directive (EU 2022/2523), which obliges EU member states to transpose the rules into national domestic law.

The date of application of the national domestic law in Germany is scheduled for the fiscal year 2024. Subsequent, when the OECD Model Rules has entered into force in Germany, the Group will be obliged to file top-up tax information returns for all entities which are part of the group, beginning with the fiscal year 2024. If in any jurisdiction the effective tax rate 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. To date, no jurisdiction in which the Group operates has transposed the OECD Model Rules into national domestic law and entered into force. The Group closely follows the progress of the legislative process in each country in which the Group operates.

F-15
2.3.7 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.

2.3.8 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.

2.3.9 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:

<table>
<thead>
<tr>
<th>Property, plant and equipment</th>
<th>Useful life (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buildings</td>
<td>10-33</td>
</tr>
<tr>
<td>Equipment, tools and installations</td>
<td>5-18</td>
</tr>
</tbody>
</table>

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 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 it is 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.

F-17
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 is not terminated early.

The lease liability is subsequently measured at amortized cost using the effective interest 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 in “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:

<table>
<thead>
<tr>
<th>Right-of-use assets</th>
<th>Useful life or shorter lease term (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buildings</td>
<td>2-25</td>
</tr>
<tr>
<td>Equipment, tools and installations</td>
<td>2-5</td>
</tr>
<tr>
<td>Production facilities</td>
<td>2-3</td>
</tr>
<tr>
<td>Automobiles</td>
<td>3-4</td>
</tr>
</tbody>
</table>

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.

2.3.1 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 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:

<table>
<thead>
<tr>
<th>Intangible assets</th>
<th>Useful Life (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intellectual property</td>
<td>8-20</td>
</tr>
<tr>
<td>rights</td>
<td></td>
</tr>
<tr>
<td>Licenses</td>
<td>3-20</td>
</tr>
<tr>
<td>Software</td>
<td>3-8</td>
</tr>
</tbody>
</table>

Intangible assets with indefinite useful lives are not amortized, but 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 2.3.14 for further details). 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, which 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.

Research and Development Costs

Research costs are expensed as incurred. Development expenditures on an individual project are recognized as an intangible asset if, and only if, all of the following six criteria can be demonstrated:

- the technical feasibility of completing the intangible asset so that the asset will be available for use or sale;
- the intention to complete the project;
- the ability and intention to use or sell the asset;
- how the asset will generate future economic benefits;
- the availability of resources to complete the asset; and
- the ability to reliably measure the expenditure during development.

Due to the inherent risk of failure in pharmaceutical development and the uncertainty of approval, management has determined that these criteria are not met in the biotech sector until regulatory approval has been obtained. The related expenditure is reflected in the consolidated statements of profit or loss in the period in which the expenditure is incurred.

Following initial recognition of the development expenditure as an asset, the asset is carried at cost less any accumulated amortization and accumulated impairment losses. Amortization of the asset begins when development is complete and the asset is available for use. It is amortized over the period of expected future benefit. Amortization is recorded in cost of sales. During the period of development, the asset is tested for impairment annually.

2.3.12 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 trade receivables, cash and cash equivalents, cash deposits with an original term of six months recognized as other financial assets as well as equity investments. Financial assets are initially measured at fair value 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 at amortized cost include trade receivables. With respect to trade receivables, we applied the practical expedient which means that they are measured at the transaction price determined under IFRS 15. Refer to the accounting policies in Note 2.3.4. Other financial assets are measured at amortized costs since they 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 when 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.

For trade receivables and contract assets, the Group applies a simplified approach in calculating ECLs. Therefore, 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. For the PD of companies, we use the maturities of the trade receivables and the scoring of the companies.

ii) Financial Liabilities

Financial liabilities are generally measured at amortized cost using the effective-interest 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 effective interest rate (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 either shown as other operating income or expenses on a cumulative basis and might switch between these two positions during the year-to-date reporting periods.

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 its shelf-life has expired. For inventories subject to the collaboration partners’ gross profit share mechanism, we consider the contractual compensation payments in the estimate of the net realizable value.

2.3.14 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 as of October 1. 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. In case the asset is not generating 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.

In assessing value in use, the estimated future cash flows 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 asset. In determining fair value less costs of disposal, recent market transactions and our market capitalization are taken into account.

If a value in use is determined it is based on detailed budgets and forecast calculations, which are prepared separately for each of our cash-generating units to which the individual assets are allocated. These budgets and forecast calculations generally cover a period of at least five years. A long-term growth rate is calculated and applied to project future cash flows after the last year of the detailed planning period.

Impairment losses are recognized in the consolidated statements of profit or loss in expense categories consistent with the function of the impaired asset.

For assets excluding goodwill, an assessment is made at each reporting date to determine whether there is an indication that previously recognized impairment losses no longer exist or have decreased. If such indication exists, the
asset’s or cash-generating unit’s recoverable amount is estimated. A previously recognized impairment loss is reversed only if there has been a change in the assumptions used to determine the asset’s recoverable amount since the last impairment loss was recognized. The reversal is limited so that the carrying amount of the asset does not exceed its recoverable amount, nor exceed the carrying amount that would have been determined, net of depreciation, had no impairment loss been recognized for the asset in prior years. Such reversal is recognized in the consolidated statements of profit or loss.

2.3.15 Cash and Cash Equivalents
Cash and cash equivalents comprise cash at banks and on hand and short-term investments we consider to be highly liquid (including deposits and money market funds) 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.

2.3.16 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.

2.3.17 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 that will ultimately vest.

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 employer’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.

F-22
2.3.18 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 shown in a separate category, Treasury Shares. Any premium paid in excess of the nominal value of a repurchased ADS is deducted from capital reserves. 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 trade and settlement date as profit or loss.

2.4 Standards Applied for the First Time

In 2022, the following potentially relevant new and amended standards and interpretations became effective, but did not have an impact on our consolidated financial statements:

<table>
<thead>
<tr>
<th>Standards / Interpretations</th>
<th>Date of application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amendments to IFRS 3 Business Combinations: Reference to the Conceptual Framework</td>
<td>January 1, 2022</td>
</tr>
<tr>
<td>Amendments to IAS 37 Provisions, Contingent Liabilities and Contingent Assets: Onerous Contracts – Cost of Fulfilling a Contract Amendments to IAS 37 Use</td>
<td>January 1, 2022</td>
</tr>
<tr>
<td>Amendments to IAS 16 Property, Plant and Equipment: Proceeds before Intended Use</td>
<td>January 1, 2022</td>
</tr>
<tr>
<td>Annual Improvements to IFRS Standards 2018-2020</td>
<td>January 1, 2022</td>
</tr>
</tbody>
</table>

2.5 Standard Issued but Not Yet Effective

The new and amended standards and interpretations that are issued, but not yet effective, up to 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.

<table>
<thead>
<tr>
<th>Standards / Interpretations</th>
<th>Date of application</th>
</tr>
</thead>
<tbody>
<tr>
<td>IFRS 17 Insurance Contracts</td>
<td>January 1, 2023</td>
</tr>
<tr>
<td>Amendments to IFRS 17 Insurance Contracts</td>
<td>January 1, 2023</td>
</tr>
<tr>
<td>Amendments to IAS 1 and IFRS Practice Statement 2: Disclosure of Accounting Policies</td>
<td>January 1, 2023</td>
</tr>
<tr>
<td>Amendments to IAS 8 Accounting policy changes: Definition of Accounting Estimates</td>
<td>January 1, 2023</td>
</tr>
<tr>
<td>Amendments to IAS 12 Income Taxes: Deferred Tax related to Assets and Liabilities arising from a Single Transaction</td>
<td>January 1, 2023</td>
</tr>
<tr>
<td>Amendments to IAS 1 Presentation of Financial Statements: Classification of Liabilities as Current or Non-Current</td>
<td>January 1, 2024</td>
</tr>
<tr>
<td>Amendments to IAS 1 Presentation of Financial Statements: Non-current Liabilities with Covenants</td>
<td>January 1, 2024</td>
</tr>
<tr>
<td>Amendments to IFRS 16 Leases: Lease Liability in a Sale and Leaseback</td>
<td>January 1, 2024</td>
</tr>
</tbody>
</table>

We do not expect a significant impact of the application of any of these standards and amendments.

3 Significant Accounting Judgments, 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 judgment 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.

F-23
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. It is assessed that 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 considerations, which are contingent on the occurrence or non-occurrence of a future event (i.e., reaching a certain milestone). When determining deferred revenues of 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, such 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 fiscal year.

Future milestone payments would become unconstrained at the satisfaction of the milestone event, specifically a development event, a 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 other than to provide a significant benefit of financing. For performance obligations in which the costs vary based on progress, an input-based measure considering cost incurred depicts most reliably the progress of the related research activities. In other cases, revenue recognition on a straight-line basis may most reliably depict 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 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 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 respectively. 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 partners’ 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. Certain of the information which our collaboration partner provides us with to identify the gross profit are, by necessity, preliminary and subject to change.

Pfizer’s gross profit shares are calculated based on sales and include consideration of transfer prices. The latter includes 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.

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 the carrying amounts of the revenue recognition-related contract balances, 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 claims and legal proceedings. Those include claims from third parties demanding indemnification for purported infringement of third party’s patent or other intellectual proprietary rights as well as product liability claims. For 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
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, to determine whether this provides additional information regarding conditions that existed at the end of the reporting period. Changes to the estimates and assumptions and outcomes that differ from these 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 and contingencies, see Note 17.

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. We have entered into agreements under which third parties grant licenses to us. If those licenses grant access to technologies, both parties jointly perform research or development activities and both are exposed to significant risks and rewards of the activities, costs incurred with the agreements are not treated differently from costs related to own product candidates. If the agreements grant us rights to use certain patents and technologies that meet the definition of an identifiable asset, they are treated as acquired intangible assets. 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 regularly 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. Sales-based milestone or royalty payments incurred under license agreements relating to self-developed intangibles after the approval date of the respective pharmaceutical product are recognized as expenses as incurred. Prior to initial regulatory approval, costs relating to production of pre-launch products which do not fulfill capitalization criteria are expensed as research and development expenses in the period incurred.

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 like a binomial or Monte-Carlo simulation model for the measurement of the cash-and-equity-settled transactions’ fair value considering certain assumption relating to, e.g., the volatility of 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 post the initial public offering, the grant date’s share prices on the Nasdaq Global Select Market were included in the valuation.

A retention assumption is applied when estimating the number of equity instruments for which service conditions are expected to be satisfied and will be revised in case material differences arise. Ultimately, a true-up to the number satisfied until settlement date will be recorded.
For further disclosures relating to share-based payments, see Note 16.

**Embedded Derivatives**

Defining the fair value of the embedded derivative which was bifurcated from the convertible note, as host contract, requires significant judgment. We used the Cox-Rubinstein binomial tree model when determining the fair value of the conversion right, the embedded derivative which was bifurcated from the convertible note, as host contract. The primary inputs used in the model include stock price volatility, credit spreads, risk-free interest rate and foreign exchange forward rates. Stock price volatility is based on our implied volatility, credit risk is model implied and adjusted for movement in credit spreads for B-rated corporates at each valuation date, the risk-free interest rate is based on currency specific time congruent IBOR and swap rates whereas the foreign exchange forward rates are based on observable market data.

For further disclosures relating to financial instruments, see Note 12.

**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 impair deferred tax assets when 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. When determining whether sufficient future taxable profit will be available against which the deductible temporary differences, tax loss carry forwards and tax credits can be utilized, significant management judgment is required. This 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. As a matter of policy, convincing evidence supporting the recognition of deferred tax assets is required if an entity has suffered a loss in either the current or the preceding periods.

Our management continued to determine 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 neither have any taxable temporary difference 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:

<table>
<thead>
<tr>
<th>Name</th>
<th>Country of Incorporation</th>
<th>Registered office</th>
<th>December 31, 2022</th>
<th>December 31, 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioNTech BioNTainer Holding GmbH</td>
<td>Germany</td>
<td>Mainz</td>
<td>100%</td>
<td>n/a</td>
</tr>
<tr>
<td>BioNTech Cell &amp; Gene Therapies GmbH</td>
<td>Germany</td>
<td>Mainz</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Delivery Technologies GmbH</td>
<td>Germany</td>
<td>Halle</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Diagnostics GmbH</td>
<td>Germany</td>
<td>Mainz</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Europe GmbH</td>
<td>Germany</td>
<td>Mainz</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Individualized mRNA Manufacturing GmbH, G.</td>
<td>Germany</td>
<td>Mainz</td>
<td>100%</td>
<td>n/a</td>
</tr>
<tr>
<td>BioNTech Innovation GmbH</td>
<td>Germany</td>
<td>Mainz</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Innovative Manufacturing Services GmbH</td>
<td>Germany</td>
<td>Idar-Oberstein</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Idar-Oberstein Services GmbH</td>
<td>Germany</td>
<td>Idar-Oberstein</td>
<td>100%</td>
<td>n/a</td>
</tr>
<tr>
<td>BioNTech Manufacturing GmbH</td>
<td>Germany</td>
<td>Mainz</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Manufacturing Marburg GmbH</td>
<td>Germany</td>
<td>Marburg</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Innovation and Services Marburg GmbH</td>
<td>Germany</td>
<td>Marburg</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>JPT Peptide Technologies GmbH</td>
<td>Germany</td>
<td>Berlin</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>NT Security and Services GmbH</td>
<td>Germany</td>
<td>Mainz</td>
<td>100%</td>
<td>n/a</td>
</tr>
<tr>
<td>reSano GmbH</td>
<td>Germany</td>
<td>Mainz</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Real Estate Holding GmbH</td>
<td>Germany</td>
<td>Holzkirchen</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Real Estate Verwaltungs GmbH</td>
<td>Germany</td>
<td>Holzkirchen</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Real Estate GmbH &amp; Co. KG</td>
<td>Germany</td>
<td>Holzkirchen</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Real Estate An der Goldgrube 12 GmbH &amp; Co. KG</td>
<td>Germany</td>
<td>Holzkirchen</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Real Estate Haus Vor GmbH &amp; Co. KG</td>
<td>Germany</td>
<td>Holzkirchen</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Real Estate An der Goldgrube 12 GmbH &amp; Co. KG</td>
<td>Germany</td>
<td>Holzkirchen</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Real Estate Adams-Opel-Stadte GmbH &amp; Co. KG</td>
<td>Germany</td>
<td>Holzkirchen</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Real Estate An der Goldgrube 12 GmbH &amp; Co. KG</td>
<td>Germany</td>
<td>Holzkirchen</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Australia Pty Ltd</td>
<td>Australia</td>
<td>Melbourne</td>
<td>100%</td>
<td>n/a</td>
</tr>
<tr>
<td>BioNTech RAD (Austria) GmbH</td>
<td>Austria</td>
<td>Vienna</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech (Shanghai) Pharmaceuticals Co. Ltd.</td>
<td>China</td>
<td>Shanghai</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Rwanda Ltd.</td>
<td>Rwanda</td>
<td>Kigali</td>
<td>100%</td>
<td>n/a</td>
</tr>
<tr>
<td>BioNTech Pharmaceuticals Asia Pacific Pte. Ltd.</td>
<td>Singapore</td>
<td>Singapore</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Turkey Tıbbi Üünder Ve Klinik Araştırması Tııızıst Anonim Şirketi</td>
<td>Turkey</td>
<td>Istanbul</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech UK Limited</td>
<td>United Kingdom</td>
<td>London (previously</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech Research and Development, Inc.</td>
<td>United States</td>
<td>Cambridge</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech USA Holding, LLC</td>
<td>United States</td>
<td>Cambridge</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>BioNTech US Inc.</td>
<td>United States</td>
<td>Cambridge</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>JPT Peptide Technologies Inc.</td>
<td>United States</td>
<td>Cambridge</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

(1) Has been incorporated during the year ended December 31, 2022.

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 enabled it to exercise the majority of voting rights to pass resolutions at our Annual General Meeting, or AGM.
Entity with significant Influence over the Group

Medine GmbH, Mainz, owned the following percentage of ordinary shares in BioNTech at the following dates as indicated:

<table>
<thead>
<tr>
<th>Name</th>
<th>Country of incorporation</th>
<th>Registered office</th>
<th>Ownership of ordinary shares in BioNTech (in %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medine GmbH</td>
<td>Germany</td>
<td>Mainz</td>
<td>Ownership of ordinary shares in BioNTech (in %)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>December 31, 2022</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>17.38%</td>
</tr>
</tbody>
</table>

5 Business Combinations

Business Combinations during the year ended December 31, 2021

BioNTech R&D (Austria) GmbH, or BioNTech Austria (previously PhagoMed Biopharma GmbH)

On October 1, 2021, BioNTech Austria, an Austrian biotechnology company, specialized in the development of a new class of antibacterials, was fully acquired to expand our infectious disease portfolio capabilities.

The total consideration comprised an upfront consideration of €50.0 million (less acquired debt) of which €23.2 million are considered remuneration and will be recognized as personnel expense over a three-year period in which services are to be provided. An additional consideration of maximum €100.0 million is dependent the achievement of certain clinical development milestones. At the acquisition date, the contingent consideration was recognized with its fair value of €5.5 million and is presented as non-current financial liabilities in the consolidated statements of financial position (see Note 12).
The final fair values and values in accordance with IFRS 3 of the identifiable net assets of BioNTech Austria as of the date of acquisition were as follows:

| Fair value recognized on acquisition BioNTech R&D (Austria) GmbH (in millions) |
|-----------------|------------------|------------------|
| **Assets**      |                  |                  |
| Intangible assets | € 43.3           |                  |
| Other non-financial assets non-current and current | 1.5 |                  |
| **Total assets** | € 44.8           |                  |
| **Liabilities** |                  |                  |
| Other non-financial liabilities non-current and current | 15.4 |                  |
| **Total liabilities** | € 15.4           |                  |
| **Total identifiable net assets at fair value** | € 29.4           |                  |
| Bargain purchase | (€ 2.2)          |                  |
| **Consideration transferred** | € 27.2           |                  |
| Cash paid | 21.7 |                  |
| Contingent consideration liability | 5.5 |                  |
| **Total consideration** | € 27.2           |                  |

<table>
<thead>
<tr>
<th>(in millions)</th>
<th>BioNTech R&amp;D (Austria) GmbH</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Transaction costs of the acquisition (included in cash flows from operating activities)</strong></td>
<td>€ (0.5)</td>
</tr>
<tr>
<td><strong>Net cash acquired (included in cash flows used in investing)</strong></td>
<td>0.9</td>
</tr>
<tr>
<td><strong>Cash paid (included in cash flow used in investing activities)</strong></td>
<td>(€ 21.7)</td>
</tr>
<tr>
<td><strong>Net cash flow on acquisition</strong></td>
<td>€ (21.3)</td>
</tr>
</tbody>
</table>

The intangible assets comprise a pre-clinical candidate, PM-477 as well as a platform.

A bargain purchase of €2.2 million was recognized in other operating income.

The consolidated statements of profit or loss include the results of BioNTech Austria since the acquisition date. From the date of acquisition through December 31, 2021, BioNTech Austria did not have any significant impact on the operating income or the revenues of the Group. The same applies if the transaction had occurred at the beginning of the reporting period.

F-30
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:

<table>
<thead>
<tr>
<th></th>
<th>2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(in millions)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial revenues</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COVID-19 vaccine revenues</td>
<td>€17,194.6</td>
<td>€18,874.0</td>
<td>€303.5</td>
</tr>
<tr>
<td>Sales to collaboration partners(^1)</td>
<td>€1,224.3</td>
<td>970.9</td>
<td>61.4</td>
</tr>
<tr>
<td>Direct product sales to customers</td>
<td>€5,184.7</td>
<td>€3,007.2</td>
<td>26.6</td>
</tr>
<tr>
<td>Share of collaboration partners’ gross profit and sales milestones</td>
<td>€12,766.2</td>
<td>€14,828.7</td>
<td>188.5</td>
</tr>
<tr>
<td>Other sales</td>
<td>€49.4</td>
<td>€67.2</td>
<td>€33.0</td>
</tr>
<tr>
<td>Research &amp; development revenues from collaborations</td>
<td>€18.0</td>
<td>€102.7</td>
<td>€178.8</td>
</tr>
<tr>
<td>Total</td>
<td>€17,310.6</td>
<td>€18,976.7</td>
<td>€482.3</td>
</tr>
</tbody>
</table>

\(^1\) Represents sales to our collaboration partners of products manufactured by us and reflects manufacturing costs and variances to the extent identified.

During the year ended December 31, 2022, revenues recognized from Pfizer Inc., or Pfizer (€13,795.8 million) and the German Federal Ministry of Health (€3,020.5 million), each account for 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) account for more than 10% of total revenues. During the year ended December 31, 2020, revenues recognized from Genentech (€49.2 million) and Pfizer (€371.5 million), accounted for more than 10% of total revenues. During the year ended December 31, 2022, based on the geographic region in which our customers and collaboration partners are located we mainly recognized revenues in the 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). During the year ended December 31, 2020, the main geographic regions were United States (€381.9 million) and Belgium (€56.2 million).

Commercial Revenues

During the year ended December 31, 2022, commercial revenues were recognized from the supply and sales of our COVID-19 vaccine worldwide. 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, submissions to pursue regulatory approvals in those countries where emergency use authorizations or equivalent were initially granted are ongoing. Pfizer has marketing and distribution rights worldwide with the exception of China, Germany and Turkey. 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-offs of inventories as well as costs related to production capacities derived from contracts with Contract Manufacturing Organizations (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 adjustment once identified and assessed highly probable. Sales to collaboration partners during the years ended December 31, 2022, 2021 and 2020, amounted to €1,224.3 million, €970.8 million and €61.4 million, respectively. During the years ended December 31, 2022, and 2021 those sales included €850.0 million and €31.0 million, respectively, related to the aforementioned manufacturing variances. (Nil with respect to sales during the year ended December 31, 2020).
Direct Product Sales to Customers

By supplying our territories during the years ended December 31, 2022, 2021 and 2020, we recognized €3,184.7 million, €3,007.2 million and €20.6 million of revenues, respectively, from direct COVID-19 vaccine sales in Germany and Turkey. 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 net figure and is recognized as collaboration revenue during the commercial phase, together with sales milestones that are recorded once the underlying thresholds are met. When determining the gross profit, manufacturing cost variances either reflected as transfer price adjustment as described above, or resulting from costs highly probable to be incurred by the partner were considered. During the year ended December 31, 2022, €12,736.2 million gross profit share has been recognized as revenues. During the year ended December 31, 2021 €14,352.1 million gross profit share and €476.6 million of sales milestones have been recognized as revenues. During the year ended December 31, 2020, we recognized €188.5 million gross profit share has been recognized as revenues.

Research and Development Revenues from Collaborations

During the year ended December 31, 2022, research and development revenues were mainly derived from our collaborations with Pfizer, Genentech Inc., or Genentech, and Sanofi S.A, or Sanofi. This includes revenues derived from our 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) which we entered during the year ended December 31, 2022.

During the year ended December 31, 2021, research and development revenues were mainly derived from our collaborations with Genentech and Pfizer.

During the year ended December 31, 2020, research and development revenues were mainly derived from our collaborations with Pfizer and Genentech.

The revenues from contracts with customers disclosed above were recognized as follows:

<table>
<thead>
<tr>
<th>Timing of revenue recognition</th>
<th>2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goods and services transferred at a point in time</td>
<td>€4,447.2</td>
<td>€4,034.3</td>
<td>€108.8</td>
</tr>
<tr>
<td>Goods and services transferred over time</td>
<td>127.2</td>
<td>113.7</td>
<td>185.0</td>
</tr>
<tr>
<td>Revenue recognition applying the sales-based or usage-based royalty recognition constraint model (1)</td>
<td>12,736.2</td>
<td>14,828.7</td>
<td>188.5</td>
</tr>
<tr>
<td>Total</td>
<td>€17,310.6</td>
<td>€18,976.7</td>
<td>€482.3</td>
</tr>
</tbody>
</table>

(1) Represents sales based on the share of the collaboration partners’ gross profit and sales milestones.

6.2 Contract Balances

<table>
<thead>
<tr>
<th>in millions</th>
<th>December 31, 2022</th>
<th>December 31, 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade and other receivables</td>
<td>€7,625.9</td>
<td>€10,963.3</td>
</tr>
<tr>
<td>Contract liabilities</td>
<td>125.5</td>
<td>195.1</td>
</tr>
<tr>
<td>Refund liabilities</td>
<td>24.4</td>
<td>90.6</td>
</tr>
</tbody>
</table>

F-32
Trade and other receivables significantly decreased from €12,381.7 million to €7,145.6 million 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 fiscal 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, 2022, our trade receivables included, in addition to the profit share for the fourth quarter of 2022, trade receivables which related to the gross profit share for the third quarter of 2022. The payment settling our gross profit share for the third quarter of 2022 (as defined by the contract) in the amount of €1,816.5 million was received from our collaboration partner subsequent to the end of the reporting period as of January 12, 2023.

Contract liabilities mainly include upfront fees received from our major collaboration and license agreements as well as advance payments received for future COVID-19 vaccine sales and other sales. The contract liabilities from collaboration and commercial supply agreements as of December 31, 2022, comprise €68.7 million remaining upfront fees from collaboration agreements, and €56.3 million of advance payments for future COVID-19 vaccine sales (as of December 31, 2021: €61.9 million of remaining upfront fees from collaborations as well as €131.9 million of advance payments for future COVID-19 vaccine sales).

During the year ended December 31, 2022, the contract liabilities changed as revenues were recognized from contract liabilities outstanding at the beginning of the year by progressing our research and development collaboration agreements as well as partially reclassified into refund liabilities (during the year ended December 31, 2021: decrease in contract liabilities by fulfilling commercial performance obligations and progressing our research and development collaboration agreements).

The refund liabilities relate to our collaboration partner and represent consideration which has been received but which will need to be refunded to the collaboration partner.

Set out below is the amount of revenue recognized for the periods indicated:

<table>
<thead>
<tr>
<th>Years ended December 31,</th>
<th>2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amounts included in contract liabilities at the beginning of the year</td>
<td>€63.1</td>
<td>€73.7</td>
<td>€58.9</td>
</tr>
</tbody>
</table>

### 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:

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2022</th>
<th>December 31, 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within one year</td>
<td>€77.1</td>
<td>€186.1</td>
</tr>
<tr>
<td>More than one year</td>
<td>48.4</td>
<td>9.0</td>
</tr>
<tr>
<td>Total</td>
<td>€125.5</td>
<td>€195.1</td>
</tr>
</tbody>
</table>

F-33
## 7 Income and Expenses
### 7.1 Costs of Sales

<table>
<thead>
<tr>
<th></th>
<th>2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of sales related to COVID-19 vaccine revenues</td>
<td>€2,960.1</td>
<td>€2,855.6</td>
<td>€35.6</td>
</tr>
<tr>
<td>Cost related to other sales</td>
<td>34.9</td>
<td>55.9</td>
<td>23.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>€2,995.0</strong></td>
<td><strong>€2,911.5</strong></td>
<td><strong>€59.3</strong></td>
</tr>
</tbody>
</table>

During the year ended December 31, 2022, cost of sales increased compared to the year ended December 31, 2021, mainly due to recognizing cost of sales from our 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 Contract Manufacturing Organizations, or CMOs, that became redundant. The effects were driven by the introduction of a new COVID-19 vaccine formulation, the switch from the monovalent vaccine to our Omicron-adapted bivalent COVID-19 vaccines and due to accelerating internal manufacturing capacities during the year ended December 31, 2022.

During the year ended December 31, 2021, cost of sales increased compared to the year ended December 31, 2020, mainly due to recognizing cost of sales from our COVID-19 vaccine sales, which included the share of gross profit that we owe our collaboration partner Pfizer based on our sales.

### 7.2 Research and Development Expenses

<table>
<thead>
<tr>
<th></th>
<th>2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchased services</td>
<td>€621.6</td>
<td>€572.6</td>
<td>€359.9</td>
</tr>
<tr>
<td>Wages, benefits and social security expense</td>
<td>385.9</td>
<td>233.1</td>
<td>126.3</td>
</tr>
<tr>
<td>Laboratory supplies</td>
<td>398.0</td>
<td>53.8</td>
<td>107.8</td>
</tr>
<tr>
<td>Depreciation and amortization</td>
<td>49.3</td>
<td>32.9</td>
<td>30.2</td>
</tr>
<tr>
<td>Other</td>
<td>82.2</td>
<td>50.8</td>
<td>20.8</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>€1,537.0</strong></td>
<td><strong>€949.2</strong></td>
<td><strong>€645.0</strong></td>
</tr>
</tbody>
</table>

During the year ended December 31, 2022, research and development expenses increased compared to the year ended December 31, 2021, mainly due to expenses in connection with the development and production of our Omicron-adapted bivalent COVID-19 vaccines and from progressing the clinical studies for our pipeline candidates. The increase was further driven by an increase in wages, benefits and social security expenses resulting from an increase in headcount as well as expenses incurred under our share-based-payment arrangements.

During the year ended December 31, 2021, research and development expenses increased compared to the year ended December 31, 2020, mainly due to increased research and development expenses from the BNT162 clinical trials launched and conducted in the year ended December 31, 2021, recorded as purchased services with respect to those expenses, which are initially incurred by Pfizer and subsequently charged to us under the collaboration agreement. The increase was further driven by an increase in wages, benefits and social security expenses resulting from an increase in headcount, recording expenses incurred under our share-based-payment arrangements as well as from recognizing inventor remuneration expenses.
7.3 Sales and Marketing Expenses

<table>
<thead>
<tr>
<th></th>
<th>Years ended December 31,</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2022</td>
<td>2021</td>
</tr>
<tr>
<td>Purchased services</td>
<td>€24.0</td>
<td>€26.5</td>
</tr>
<tr>
<td>IT costs</td>
<td>11.2</td>
<td>5.0</td>
</tr>
<tr>
<td>Wages, benefits and social security expense</td>
<td>7.8</td>
<td>4.3</td>
</tr>
<tr>
<td>Other</td>
<td>16.5</td>
<td>14.6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>€59.5</strong></td>
<td><strong>€50.4</strong></td>
</tr>
</tbody>
</table>

During the year ended December 31, 2022, sales and marketing expenses increased compared to the year ended December 31, 2021, mainly due to increased expenses for IT consulting and an increase in wages, benefits and social security expenses resulting from an increase in headcount.

During the year ended December 31, 2021, sales and marketing expenses increased compared to the year ended December 31, 2020, mainly due to an increase in purchased service which we incurred in connection with our COVID-19 vaccine commercial activities.

7.4 General and Administrative Expenses

<table>
<thead>
<tr>
<th></th>
<th>Years ended December 31,</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2022</td>
<td>2021</td>
</tr>
<tr>
<td>Wages, benefits and social security expense</td>
<td>€145.9</td>
<td>€90.5</td>
</tr>
<tr>
<td>Purchased services</td>
<td>143.9</td>
<td>70.2</td>
</tr>
<tr>
<td>IT and office equipment</td>
<td>88.1</td>
<td>25.1</td>
</tr>
<tr>
<td>Insurance premiums</td>
<td>21.3</td>
<td>30.4</td>
</tr>
<tr>
<td>Other</td>
<td>85.5</td>
<td>69.6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>€484.7</strong></td>
<td><strong>€285.8</strong></td>
</tr>
</tbody>
</table>

During the year ended December 31, 2022, general and administrative expenses increased compared to the year ended December 31, 2021, mainly due to increased expenses for IT consulting and IT services, increased expenses for purchased management consulting and legal services as well as an increase in wages, benefits and social security expenses resulting mainly from an increase in headcount. Our business development transactions also contributed to the increase in general and administrative expenses.

During the year ended December 31, 2021, general and administrative expenses increased compared to the year ended December 31, 2020, mainly due to an increase in wages, benefits and social security expenses resulting from an increase in headcount and expenses incurred under the share-based payment arrangements, increased expenses for purchased management consulting and legal services as well as higher insurance premiums caused by increased business volume.

7.5 Other Operating Expenses

<table>
<thead>
<tr>
<th></th>
<th>Years ended December 31,</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2022</td>
<td>2021</td>
</tr>
<tr>
<td>Loss on derivative instruments at fair value through profit or loss</td>
<td>€385.7</td>
<td>€38.3</td>
</tr>
<tr>
<td>Other</td>
<td>21.5</td>
<td>8.1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>€407.2</strong></td>
<td><strong>€46.4</strong></td>
</tr>
</tbody>
</table>

F-35
During the year ended December 31, 2022, the other 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.

During the year ended December 31, 2021, the other operating expenses increased compared to the year ended December 31, 2020, mainly from recording the change in fair value of foreign exchange forward contracts.

7.6 Other Operating Income

<table>
<thead>
<tr>
<th></th>
<th>Years ended December 31, 2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreign exchange differences, net</td>
<td>€727.4</td>
<td>€446.3</td>
<td>—</td>
</tr>
<tr>
<td>Government grants</td>
<td>1.4</td>
<td>157.2</td>
<td>239.0</td>
</tr>
<tr>
<td>Gain on derivative instruments at fair value through profit or loss</td>
<td>—</td>
<td>5.7</td>
<td>—</td>
</tr>
<tr>
<td>Other</td>
<td>86.5</td>
<td>9.2</td>
<td>11.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>€815.3</td>
<td>€598.4</td>
<td>€250.5</td>
</tr>
</tbody>
</table>

During the year ended December 31, 2022, the other income increased compared to the year ended December 31, 2021, which was mainly due from 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.

During the year ended December 31, 2021, the other income increased compared to the year ended December 31, 2020, which was mainly due from recognizing foreign exchange differences and government grant funding. The government grant funding mainly related to an initiative by the German Federal Ministry of Education (Bundesministerium für Bildung und Forschung, or the BMBF) to support our COVID-19 vaccine program, BNT162. During the year ended December 31, 2021, the final draw downs were made. The government funding from the BMBF amounted in total to €375.0 million during the years ended December 31, 2021, and 2020.

7.7 Finance Income

<table>
<thead>
<tr>
<th></th>
<th>Years ended December 31, 2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fair value adjustments of financial instruments measured at fair value</td>
<td>€216.8</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Foreign exchange differences, net</td>
<td>65.0</td>
<td>66.2</td>
<td>—</td>
</tr>
<tr>
<td>Interest income</td>
<td>48.5</td>
<td>1.5</td>
<td>1.6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>€330.3</td>
<td>€87.7</td>
<td>€2.6</td>
</tr>
</tbody>
</table>

During the year ended December 31, 2022, the finance income increased compared to the year ended December 31, 2021, mainly due to 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 increased interest income from our bank deposits.
7.8 Finance Expenses

<table>
<thead>
<tr>
<th>Years ended December 31,</th>
<th>2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interest expenses related to financial assets</td>
<td>€2.5</td>
<td>€2.5</td>
<td>—</td>
</tr>
<tr>
<td>Interest expenses related to lease liabilities</td>
<td>5.1</td>
<td>2.9</td>
<td>2.0</td>
</tr>
<tr>
<td>Amortization of financial instruments</td>
<td>2.7</td>
<td>3.1</td>
<td>3.1</td>
</tr>
<tr>
<td>Fair value adjustments of financial instruments measured at fair value</td>
<td>—</td>
<td>277.8</td>
<td>17.3</td>
</tr>
<tr>
<td>Total</td>
<td>18.9</td>
<td>305.1</td>
<td>65.0</td>
</tr>
</tbody>
</table>

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.

7.9 Employee Benefits Expense

<table>
<thead>
<tr>
<th>Years ended December 31,</th>
<th>2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wages and salaries</td>
<td>€544.8</td>
<td>€345.9</td>
<td>€160.7</td>
</tr>
<tr>
<td>Social security costs</td>
<td>58.6</td>
<td>31.7</td>
<td>17.9</td>
</tr>
<tr>
<td>Pension costs</td>
<td>2.1</td>
<td>1.2</td>
<td>0.8</td>
</tr>
<tr>
<td>Total</td>
<td>605.5</td>
<td>378.8</td>
<td>179.4</td>
</tr>
</tbody>
</table>

Wages and salaries include, among other things, expenses for share-based payments.

8 Income Tax

Income tax for the years ended December 31, 2022, December 31, 2021, and December 31, 2020, 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 27.25% in the year ended December 31, 2022 (during the years ended December 31, 2021 and 2020: 30.72% and 30.79%, respectively). Deferred taxes are calculated at a rate of 27.2%. Deferred taxes for Austria are calculated at a corporate tax rate of 25.0%. Austria’s decrease of its corporate tax rate down to 23.0% in 2024 will be recognized from 2023 onwards. 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 4.7%). 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:

<table>
<thead>
<tr>
<th>Years ended December 31,</th>
<th>2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current income taxes</td>
<td>€3,629.6</td>
<td>€4,535.0</td>
<td>—</td>
</tr>
<tr>
<td>Deferred taxes</td>
<td>(109.9)</td>
<td>218.9</td>
<td>(161.0)</td>
</tr>
<tr>
<td>Income taxes</td>
<td>€3,519.7</td>
<td>€4,753.9</td>
<td>(161.0)</td>
</tr>
</tbody>
</table>

The following table reconciles the expected income taxes to the actual current income taxes and deferred taxes as presented in the table above. 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.
<table>
<thead>
<tr>
<th>(in millions)</th>
<th>2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Profit / (Loss) before tax</td>
<td>€12,954.1</td>
<td>€15,046.4</td>
<td>(145.8)</td>
</tr>
<tr>
<td>Expected tax credit / (benefit)</td>
<td>€3,529.7</td>
<td>€4,622.5</td>
<td>(44.9)</td>
</tr>
</tbody>
</table>

**Effects**

- Deviation due to local tax basis: 8.9, 9.1, 0.6
- Deviation due to deviating income tax rate (Germany and foreign countries): 7.3, 9.4, 1.3
- Change in valuation allowance: 36.6, 3.0, (26.2)
- Change in deferred taxes due to tax rate change: (2.3), (7.5)
- Non-deductible expenses: 2.5, 90.5, 0.8
- Non-tax-effective income: (87.9), (0.3), —
- Non-tax-effective share-based payment expenses: 8.7, 15.5, 9.8
- Tax-effective equity transaction costs: —, (1.2), (10.2)
- Adjustment prior year taxes: (31.5), (2.9), 0.3
- Non-tax-effective bargain purchase: —, (0.7), (2.2)
- Other effects: 30.5, (3.0), 0.1

**Income taxes**

- €3,519.7, €4,753.9, €(161.0)

**Effective tax rate**

- 27.2%, 31.6%, n.m.

---

(1) Certain amounts have been combined in the prior period to conform with the current period presentation.

(2) The information is not meaningful due to the loss before tax in the respective period.

The non-tax effective income of €87.9 million mainly contained the finance income effect of 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.

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. Tax expenses on the settlement are only recognized once the option rights have been exercised. After considering the settlement in the three months ended December 31, 2022, a deferred tax asset remained in our consolidated statement of financial position of €33.4 million which relates to future settlements. As the current tax effect resulting from the settlement exceeded the amount of the related cumulative remuneration expense, the current tax associated with the excess was directly recognized in equity in the amount of €368.8 million.
The settlement mechanism of the LTI-plus program (see Note 16.1 for plan details) in the course of the three months ended December 31, 2022, led to a decrease in payable income taxes in the amount of €14.0 million. Thereof current income taxes in the total amount of €8.7 million were recognized in our consolidated financial statements of profit or loss to the extent expenses have been recognized with an effect of profit and loss in the past. As the current tax effect resulting from the settlement exceeded the amount of the related cumulative remuneration expense, the current tax associated with the excess was directly recognized in equity in the amount of €5.3 million.

The current actual tax savings associated with the excess were directly recognized in equity in a total amount of €374.1 million. Considering these tax amounts directly recognized in equity when calculating an effective tax rate, the tax rate would be decreased by about three percentage points.

Taxes

Deferred taxes for the periods indicated relate to the following:

<table>
<thead>
<tr>
<th>Year ended December 31, 2022</th>
<th>January 1, 2022</th>
<th>Recognized in P&amp;L</th>
<th>Recognized in OCI</th>
<th>Recognized directly in equity</th>
<th>December 31, 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fixed assets</td>
<td>€ (6.5)</td>
<td>€ 22.1</td>
<td>€ —</td>
<td>€ —</td>
<td>€ 15.8</td>
</tr>
<tr>
<td>Right-of-use assets</td>
<td>(47.5)</td>
<td>(8.3)</td>
<td>—</td>
<td>—</td>
<td>(55.8)</td>
</tr>
<tr>
<td>Inventories</td>
<td>1.8</td>
<td>147.1</td>
<td>—</td>
<td>148.9</td>
<td></td>
</tr>
<tr>
<td>Trade and other receivables</td>
<td>(95.6)</td>
<td>(67.1)</td>
<td>—</td>
<td>(162.7)</td>
<td></td>
</tr>
<tr>
<td>Contract liabilities</td>
<td>10.6</td>
<td>(20.6)</td>
<td>—</td>
<td>(10.0)</td>
<td></td>
</tr>
<tr>
<td>Lease liabilities, loans and borrowings</td>
<td>71.8</td>
<td>(9.0)</td>
<td>—</td>
<td>62.8</td>
<td></td>
</tr>
<tr>
<td>Net employee defined benefit liabilities</td>
<td>0.9</td>
<td>(0.5)</td>
<td>0.3</td>
<td>0.7</td>
<td></td>
</tr>
<tr>
<td>Share-based payments</td>
<td>8.5</td>
<td>—</td>
<td>179.9</td>
<td>188.4</td>
<td></td>
</tr>
<tr>
<td>Other provisions</td>
<td>6.3</td>
<td>4.7</td>
<td>—</td>
<td>11.0</td>
<td></td>
</tr>
<tr>
<td>Other (incl. deferred expenses)</td>
<td>1.6</td>
<td>59.9</td>
<td>—</td>
<td>61.5</td>
<td></td>
</tr>
<tr>
<td>Tax losses / tax credits</td>
<td>70.9</td>
<td>28.6</td>
<td>—</td>
<td>99.5</td>
<td></td>
</tr>
</tbody>
</table>

Deferred tax assets net (before valuation adjustment) = € 14.3 + € 165.6 + € 0.3 + € 179.9 = € 380.1

Valuation adjustment = (81.0) + (55.7) = (136.7)

Deferred tax assets (liabilities), net (after valuation adjustment) = € 66.7 + € 109.9 + € 0.3 + € 179.9 + € 233.4

Thereof deferred tax liability = € 66.7 + € 48.3 + € 0.3 + € — + € (6.2)

F-39
### Table of Contents

**Year ended December 31, 2021**

<table>
<thead>
<tr>
<th>(in millions)</th>
<th>January 1, 2021</th>
<th>Recognized in P&amp;L</th>
<th>Recognized in OCI</th>
<th>December 31, 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fixed assets</td>
<td>€ 5.6</td>
<td>€ (1.3)</td>
<td>€ —</td>
<td>€ (10.8)</td>
</tr>
<tr>
<td>Right-of-use assets</td>
<td>(30.0)</td>
<td>(17.5)</td>
<td>—</td>
<td>(47.5)</td>
</tr>
<tr>
<td>Inventories</td>
<td>1.0</td>
<td>0.8</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Trade and other receivables</td>
<td>(3.0)</td>
<td>(92.6)</td>
<td>—</td>
<td>(95.6)</td>
</tr>
<tr>
<td>Lease liabilities</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Lease liabilities, loans and borrowings</td>
<td>25.9</td>
<td>45.9</td>
<td>—</td>
<td>71.8</td>
</tr>
<tr>
<td>Contract liabilities</td>
<td>23.4</td>
<td>(12.8)</td>
<td>—</td>
<td>10.6</td>
</tr>
<tr>
<td>Net employee defined benefit liabilities</td>
<td>0.8</td>
<td>0.1</td>
<td>—</td>
<td>0.9</td>
</tr>
<tr>
<td>Other provisions</td>
<td>1.5</td>
<td>4.8</td>
<td>—</td>
<td>6.3</td>
</tr>
<tr>
<td>Other (incl. deferred expenses)</td>
<td>10.6</td>
<td>(9.0)</td>
<td>—</td>
<td>3.6</td>
</tr>
<tr>
<td>Tax losses / tax credits</td>
<td>175.7</td>
<td>(106.8)</td>
<td>—</td>
<td>70.9</td>
</tr>
<tr>
<td>Deferred tax assets net (before valuation adjustment)</td>
<td>€ 211.5</td>
<td>€ (188.4)</td>
<td>—</td>
<td>€ 14.3</td>
</tr>
<tr>
<td>Valuation adjustment</td>
<td>(10.7)</td>
<td>(18.5)</td>
<td>—</td>
<td>(11.6)</td>
</tr>
<tr>
<td>Deferred tax assets / (liabilities), net (after valuation adjustment)</td>
<td>€ 161.0</td>
<td>€ (218.9)</td>
<td>—</td>
<td>€ (66.7)</td>
</tr>
</tbody>
</table>

As of December 31, 2022, our accumulated tax losses comprised tax losses of German entities not within the tax group (as of December 31, 2022: BioNTech BioNTainer Holding GmbH and BioNTech Idar-Oberstein Services GmbH, NT Security and Services GmbH, BioNTech Real Estate Verwaltungs GmbH and the Real Estate partnerships; as of December 31, 2021: BioNTech Innovation and Services Marburg GmbH, BioNTech Innovation GmbH, BioNTech Real Estate Verwaltungs GmbH and the Real Estate partnerships; and U.S. tax group. Up until the year ended December 31, 2021, our accumulated tax losses also comprised those of the German tax group. Our accumulated tax losses for the periods indicated amounted to the following:

<table>
<thead>
<tr>
<th>(in millions)</th>
<th>2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corporate tax</td>
<td>€ 352.3</td>
<td>€ 272.0</td>
<td>€ 596.4</td>
</tr>
<tr>
<td>Trade tax</td>
<td>204.1</td>
<td>170.6</td>
<td>513.6</td>
</tr>
</tbody>
</table>

Up until the year ended December 31, 2022, deferred tax assets on tax losses had not been recognized, as there was not sufficient probability in terms of IAS 12 that there would have been future taxable profits available against which the unused tax losses could have been utilized.

During the year ended December 31, 2021, deferred tax assets on tax losses which had been recognized for the losses incurred by the German tax group were fully utilized (as per the end of each quarter during the year ended December 31, 2021, a proportionate amount of the deferred tax assets related to the tax loss carryforward was utilized). The change in deferred taxes was also supplemented by deferred taxes on temporary differences.

F-40
Since December 2020, our COVID-19 vaccine has been fully approved, granted conditional marketing authorization, or approved or authorized for emergency or temporary use in over 100 countries and regions worldwide, which resulted in recognition of revenues from the commercial sale of pharmaceutical products for the first time. Therefore as of December 31, 2020, it was considered highly probable that taxable profits for the German tax group would be available against which the tax losses could be utilized. On this basis, we had recognized deferred tax assets and liabilities with a net amount of €161.0 million for the cumulative tax losses and temporary differences determined for the German tax group as of December 31, 2020.

The intended settlement mechanism of Option Rights of the Chief Executive Officer Grant (see Note 16.4 for plan details) led, based on IAS 12, to a deferred tax asset in the total amount of €133.6 million as of December 31, 2022. Thereof a deferred tax asset in the amount of €64.4 million is recognized as income taxes in our consolidated statements of profit or loss to the extent expenses have been recognized with an effect of profit and loss in the past. In accordance with IAS 12.68c, the remainder in the amount of €147.2 million is recognized directly in equity as other reserves in our consolidated statements of changes in stockholders’ equity.

As of December 31, 2022, we have not recognized deferred tax assets for unused tax losses and temporary differences at amount of €136.7 million (December 31, 2021: €81.0 million December 31, 2020: €50.5 million) as there is not sufficient probability in terms of IAS 12 that there will be future taxable income available against which the unused tax losses and temporary differences can be utilized.

These amounts included tax losses at an amount of €304.0 million U.S. federal tax losses and €184.6 million US state tax losses (December 31, 2021: €238.1 million U.S. federal tax losses and €147.4 million U.S. state tax losses, December 31, 2020: €136.8 million U.S. federal tax losses and €60.9 million U.S. state tax losses) related to the US tax group, thereof €24.0 million U.S. federal losses and thereof €179.0 million U.S. state tax losses that begin to expire at various dates beginning in 2033. All other material unused tax losses and temporary differences can be carried forward indefinitely.

### 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:

<table>
<thead>
<tr>
<th></th>
<th>Years ended December 31, 2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Profit attributable to ordinary equity holders of the parent for basic earnings</td>
<td>€9,434.4</td>
<td>€10,292.5</td>
<td>€15.2</td>
</tr>
<tr>
<td>Weighted average number of ordinary shares outstanding for basic EPS</td>
<td>243.3</td>
<td>244.0</td>
<td>235.4</td>
</tr>
<tr>
<td>Effects of dilution from share options</td>
<td>6.5</td>
<td>15.7</td>
<td>13.1</td>
</tr>
<tr>
<td>Weighted average number of ordinary shares outstanding adjusted for the effect of dilution</td>
<td>249.8</td>
<td>259.7</td>
<td>248.5</td>
</tr>
<tr>
<td>Earnings per share</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic profit for the period per share</td>
<td>€38.78</td>
<td>€42.18</td>
<td>€0.06</td>
</tr>
<tr>
<td>Diluted profit for the period per share</td>
<td>€37.77</td>
<td>€39.63</td>
<td>€0.06</td>
</tr>
</tbody>
</table>
## Table of Contents

10 Property, Plant and Equipment

<table>
<thead>
<tr>
<th>(in millions)</th>
<th>Land and buildings</th>
<th>Equipment, tools and installations</th>
<th>Construction in progress and advance payments</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acquisition and production costs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>As of January 1, 2021</td>
<td>€ 61.3</td>
<td>€ 142.4</td>
<td>€ 81.6</td>
<td>€285.3</td>
</tr>
<tr>
<td>Additions</td>
<td>20.0</td>
<td>44.3</td>
<td>63.2</td>
<td>127.5</td>
</tr>
<tr>
<td>Disposals</td>
<td>(0.8)</td>
<td>(15.1)</td>
<td>(1.7)</td>
<td>(17.6)</td>
</tr>
<tr>
<td>Reclassifications</td>
<td>23.1</td>
<td>25.8</td>
<td>(48.9)</td>
<td>—</td>
</tr>
<tr>
<td>Currency differences</td>
<td>0.3</td>
<td>0.7</td>
<td>0.1</td>
<td>1.3</td>
</tr>
<tr>
<td>Acquisition of subsidiaries and businesses</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>As of December 31, 2021</strong></td>
<td>€ 104.1</td>
<td>€ 198.3</td>
<td>€ 94.3</td>
<td>€396.7</td>
</tr>
<tr>
<td>As of January 1, 2022</td>
<td>104.1</td>
<td>198.3</td>
<td>94.3</td>
<td>396.7</td>
</tr>
<tr>
<td>Additions</td>
<td>100.2</td>
<td>46.7</td>
<td>182.3</td>
<td>329.2</td>
</tr>
<tr>
<td>Disposals</td>
<td>—</td>
<td>(1.3)</td>
<td>(0.5)</td>
<td>(1.6)</td>
</tr>
<tr>
<td>Reclassifications</td>
<td>12.0</td>
<td>28.2</td>
<td>(40.2)</td>
<td>—</td>
</tr>
<tr>
<td>Currency differences</td>
<td>0.7</td>
<td>0.9</td>
<td>(0.4)</td>
<td>1.2</td>
</tr>
<tr>
<td><strong>As of December 31, 2022</strong></td>
<td>€ 217.8</td>
<td>€ 273.0</td>
<td>€ 235.5</td>
<td>€725.5</td>
</tr>
<tr>
<td><strong>Cumulative depreciation and impairment charges</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>As of January 1, 2021</td>
<td>€ 10.4</td>
<td>€ 47.9</td>
<td>—</td>
<td>€ 58.3</td>
</tr>
<tr>
<td>Depreciation</td>
<td>4.4</td>
<td>25.0</td>
<td>—</td>
<td>29.4</td>
</tr>
<tr>
<td>Disposals</td>
<td>(0.6)</td>
<td>(13.1)</td>
<td>—</td>
<td>(13.7)</td>
</tr>
<tr>
<td>Currency differences</td>
<td>—</td>
<td>0.2</td>
<td>—</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>As of December 31, 2021</strong></td>
<td>€ 14.2</td>
<td>€ 60.0</td>
<td>—</td>
<td>€ 74.2</td>
</tr>
<tr>
<td>As of January 1, 2022</td>
<td>14.2</td>
<td>60.0</td>
<td>—</td>
<td>74.2</td>
</tr>
<tr>
<td>Depreciation</td>
<td>7.8</td>
<td>34.6</td>
<td>—</td>
<td>42.4</td>
</tr>
<tr>
<td>Disposals</td>
<td>—</td>
<td>(0.4)</td>
<td>—</td>
<td>(0.4)</td>
</tr>
<tr>
<td>Currency differences</td>
<td>—</td>
<td>0.1</td>
<td>—</td>
<td>0.1</td>
</tr>
<tr>
<td><strong>As of December 31, 2022</strong></td>
<td>€ 22.0</td>
<td>€ 94.3</td>
<td>—</td>
<td>€116.3</td>
</tr>
<tr>
<td><strong>Carrying amount</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>As of December 31, 2021</td>
<td>€ 89.9</td>
<td>€ 138.3</td>
<td>€ 94.3</td>
<td>€322.5</td>
</tr>
<tr>
<td>As of December 31, 2022</td>
<td>€ 195.0</td>
<td>€ 178.7</td>
<td>€ 235.5</td>
<td>€609.2</td>
</tr>
</tbody>
</table>

F-42
## Intangible Assets

### Acquisition costs

<table>
<thead>
<tr>
<th></th>
<th>Goodwill</th>
<th>Concessions, licenses, in-process R&amp;D and similar rights</th>
<th>Advance payments</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>As of January 1, 2021</td>
<td>€ 53.7</td>
<td>€ 147.2</td>
<td>€ 6.0</td>
<td>€206.9</td>
</tr>
<tr>
<td>Additions</td>
<td>—</td>
<td>5.9</td>
<td>4.2</td>
<td>10.1</td>
</tr>
<tr>
<td>Disposals</td>
<td>—</td>
<td>(8.5)</td>
<td>(1.2)</td>
<td>(9.7)</td>
</tr>
<tr>
<td>Reclassifications</td>
<td>—</td>
<td>1.2</td>
<td>(1.2)</td>
<td>—</td>
</tr>
<tr>
<td>Currency differences</td>
<td>4.1</td>
<td>2.5</td>
<td>—</td>
<td>6.6</td>
</tr>
<tr>
<td>Acquisition of subsidiaries and businesses</td>
<td>—</td>
<td>43.3</td>
<td>—</td>
<td>43.3</td>
</tr>
<tr>
<td>As of December 31, 2021</td>
<td>€ 57.8</td>
<td>€ 191.6</td>
<td>€ 7.8</td>
<td>€257.2</td>
</tr>
<tr>
<td>As of January 1, 2022</td>
<td>57.8</td>
<td>191.6</td>
<td>7.8</td>
<td>257.2</td>
</tr>
<tr>
<td>Additions</td>
<td>—</td>
<td>22.8</td>
<td>11.4</td>
<td>34.2</td>
</tr>
<tr>
<td>Disposals</td>
<td>—</td>
<td>(0.1)</td>
<td>—</td>
<td>(0.1)</td>
</tr>
<tr>
<td>Reclassifications</td>
<td>—</td>
<td>6.1</td>
<td>(6.1)</td>
<td>—</td>
</tr>
<tr>
<td>Currency differences</td>
<td>3.4</td>
<td>1.9</td>
<td>—</td>
<td>5.3</td>
</tr>
<tr>
<td>As of December 31, 2022</td>
<td>€ 61.2</td>
<td>€ 222.3</td>
<td>€ 13.1</td>
<td>€298.6</td>
</tr>
</tbody>
</table>

### Cumulative amortization and impairment charges

<table>
<thead>
<tr>
<th></th>
<th>Goodwill</th>
<th>Concessions, licenses, in-process R&amp;D and similar rights</th>
<th>Advance payments</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>As of January 1, 2021</td>
<td>—</td>
<td>€ 43.4</td>
<td>—</td>
<td>€43.4</td>
</tr>
<tr>
<td>Amortization</td>
<td>—</td>
<td>16.8</td>
<td>—</td>
<td>16.8</td>
</tr>
<tr>
<td>Disposals</td>
<td>—</td>
<td>(5.5)</td>
<td>—</td>
<td>(5.5)</td>
</tr>
<tr>
<td>Currency differences</td>
<td>—</td>
<td>0.1</td>
<td>—</td>
<td>0.1</td>
</tr>
<tr>
<td>As of December 31, 2021</td>
<td>—</td>
<td>€ 54.8</td>
<td>—</td>
<td>€54.8</td>
</tr>
<tr>
<td>As of January 1, 2022</td>
<td>—</td>
<td>54.8</td>
<td>—</td>
<td>54.8</td>
</tr>
<tr>
<td>Amortization</td>
<td>—</td>
<td>22.0</td>
<td>—</td>
<td>22.0</td>
</tr>
<tr>
<td>Disposals</td>
<td>—</td>
<td>(0.1)</td>
<td>—</td>
<td>(0.1)</td>
</tr>
<tr>
<td>Currency differences</td>
<td>—</td>
<td>0.2</td>
<td>—</td>
<td>0.2</td>
</tr>
<tr>
<td>As of December 31, 2022</td>
<td>—</td>
<td>€ 76.9</td>
<td>—</td>
<td>€76.9</td>
</tr>
</tbody>
</table>

### Carrying amount

<table>
<thead>
<tr>
<th></th>
<th>Goodwill</th>
<th>Concessions, licenses, in-process R&amp;D and similar rights</th>
<th>Advance payments</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>As of December 31, 2021</td>
<td>€ 57.8</td>
<td>€ 136.8</td>
<td>€ 7.8</td>
<td>€202.4</td>
</tr>
<tr>
<td>As of December 31, 2022</td>
<td>€ 61.2</td>
<td>€ 145.4</td>
<td>€ 13.1</td>
<td>€219.7</td>
</tr>
</tbody>
</table>
For the year ended December 31, 2022, we have total Goodwill of €61.2 million, which relates almost completely to the CGU immunotherapies. The CGU immunotherapies focus on the development of therapies to address a range of rare and infectious diseases and include our broad pipeline that includes mRNA-based immune activators, antigen-targeting T cells and antibodies, and defined immunomodulators of various immune cell mechanisms.

The recoverable amount of the CGU immunotherapies has been determined based on a fair value less cost of disposal (FVLCD) derived from our market capitalization as observable input parameter. As a result of the analysis, management did not identify an impairment for this CGU.

We concluded that no reasonable possible change of the recoverable amount would cause the carrying amount of the CGU Immunotherapies to exceed its recoverable amount.

Non-Current Assets by Region

As of December 31, 2022, non-current assets comprised €188.0 million intangible assets, property, plant and equipment, right-of-use assets and other assets of our subsidiaries incorporated in the United States (as of December 31, 2021: €139.7 million). The remaining non-current assets mainly relate to subsidiaries 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 on a regular basis. As part of this review, the committee considers the total cash and cash equivalents, the 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.

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2022</th>
<th>December 31, 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash at banks and on hand</td>
<td>€ 1,325.2</td>
<td>€ 1,092.7</td>
</tr>
<tr>
<td>Cash equivalents</td>
<td>€ 12,549.9</td>
<td>€ 600.0</td>
</tr>
<tr>
<td>Bank deposits</td>
<td>€ 9,401.0</td>
<td>€ 600.0</td>
</tr>
<tr>
<td>Money market funds</td>
<td>€ 3,148.9</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>€ 13,875.1</td>
<td>€ 1,692.7</td>
</tr>
</tbody>
</table>

In general, the aim is to 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, which requires that our investment portfolio shall be maintained in a manner that minimizes risk of 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 efficiently by the Treasury department.

We are not subject to externally imposed capital requirements. Our capital management objectives were achieved in the reporting year.

12.2 Categories of Financial Instruments

Financial Assets: Financial Assets at Amortized Cost and at Fair Value through OCI and Profit or Loss

Set out below, is an overview of financial assets at amortized cost and at fair value through OCI and profit or loss, other than cash and cash equivalents, held by the Group as of the dates indicated:

<table>
<thead>
<tr>
<th>Financial assets</th>
<th>December 31, 2022</th>
<th>December 31, 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Derivatives not designated as hedging instruments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foreign exchange forward contracts</td>
<td>€ 183.7</td>
<td>€ 5.7</td>
</tr>
<tr>
<td>Equity instruments designated at fair value through OCI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-listed equity investments</td>
<td>57.1</td>
<td>19.5</td>
</tr>
<tr>
<td>Listed equity investments</td>
<td>20.0</td>
<td>—</td>
</tr>
<tr>
<td>Financial assets at amortized cost</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade and other receivables</td>
<td>7,145.6</td>
<td>12,381.7</td>
</tr>
<tr>
<td>Cash deposit with an original term of six months</td>
<td>375.2</td>
<td>375.2</td>
</tr>
<tr>
<td>Other financial assets</td>
<td>8.8</td>
<td>2.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>€ 7,415.2</td>
<td>€ 12,784.6</td>
</tr>
<tr>
<td>Total current</td>
<td>€ 7,335.0</td>
<td>€ 12,763.3</td>
</tr>
<tr>
<td>Total non-current</td>
<td>80.2</td>
<td>21.3</td>
</tr>
</tbody>
</table>

Derivatives Not Designated as Hedging Instruments

Derivatives not designated as hedging instruments relate to foreign exchange forward contracts that were entered into during the years ended December 31, 2022, and 2021, to manage some of our foreign currency exposures. The foreign exchange forward contracts are measured at fair value through profit or loss and are intended to reduce the exposure to foreign currency risk resulting from trade receivables denominated in U.S. dollar.
In January 2022, we acquired 13.0% of the shares (fully diluted as of closing) of Crescendo Biologics Ltd., a private, clinical-stage immuno-oncology company developing novel, targeted T-cell enhancing Humabody therapeutics headquartered in Cambridge, United Kingdom. The equity investment complements a collaboration to develop novel immunotherapies for the treatment of patients with cancer and other diseases.

In November 2022, we acquired 8.3% of the shares (fully diluted as of closing) leading to 7.1% of the voting rights, of Ryvu Therapeutics S.A., a listed clinical-stage drug discovery and development company focused on novel small-molecule therapies that address emerging targets in oncology headquartered in Krakow, Poland. The equity investment complements a multi-target research collaboration to develop multiple small molecule programs targeting immune modulation in cancer and potentially other disease areas.

In accordance with IFRS 9, we elected to present changes in fair value of these equity investments in OCI to avoid fluctuation to be disclosed in our consolidated financial statements of profit or loss.

In connection with the agreement announced in January 2023, under which we plan to acquire, subject to the satisfaction of customary closing conditions and certain regulatory approvals, all remaining shares of InstaDeep Ltd., or InstaDeep, a leading global technology company in the field of artificial intelligence (“AI”) and machine learning. The fair value of our stake in InstaDeep which was initially acquired during the year ended December 31, 2021, was remeasured based on the preliminary estimate of the expected purchase price.

Since the acquisition date, no material gains and losses on our equity investments in Crescendo Biologics Ltd. and Ryvu Therapeutics S.A. have occurred.

Financial Assets at Amortized Cost
Trade and other receivables remained outstanding as of December 31, 2022, mainly due to the contractual settlement of the gross profit share under our COVID-19 collaboration with Pfizer as described in Note 6.2 as well as from our direct product sales to customers in our territory.

Financial Liabilities: Financial Liabilities at Amortized Cost and at Fair Value through Profit or Loss (including Loans and Borrowings and Other Financial Liabilities)
Set out below, is an overview of financial liabilities, other financial liabilities and trade payables held by the Group as of the dates indicated:

<table>
<thead>
<tr>
<th>Description</th>
<th>December 31, 2022</th>
<th>December 31, 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lease liabilities</td>
<td>€ 210.1</td>
<td>€ 181.6</td>
</tr>
<tr>
<td>Convertible note – host contract(1)</td>
<td>—</td>
<td>99.7</td>
</tr>
<tr>
<td>Loans and borrowings</td>
<td>2.1</td>
<td>20.2</td>
</tr>
<tr>
<td>Total</td>
<td>€ 212.2</td>
<td>€ 301.5</td>
</tr>
<tr>
<td>Total current</td>
<td>3.1</td>
<td>30.7</td>
</tr>
<tr>
<td>Total non-current</td>
<td>179.1</td>
<td>270.8</td>
</tr>
</tbody>
</table>

(1) The convertible note was fully redeemed by exercising our early redemption option as of March 1, 2022, the redemption date.
### Other Financial Liabilities

<table>
<thead>
<tr>
<th>(in millions)</th>
<th>December 31, 2022</th>
<th>December 31, 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Derivatives not designated as hedging instruments</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Convertible note – embedded derivative(1)</td>
<td>€ —</td>
<td>€ 308.7</td>
</tr>
<tr>
<td>Financial liabilities at fair value through profit or loss</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foreign exchange forward contracts</td>
<td>—</td>
<td>63.0</td>
</tr>
<tr>
<td>Contingent consideration</td>
<td>6.1</td>
<td>6.1</td>
</tr>
<tr>
<td><strong>Total financial liabilities at fair value</strong></td>
<td>€ 6.1</td>
<td>€ 377.5</td>
</tr>
<tr>
<td><strong>Trade payables and other financial liabilities at amortized cost, other than loans and borrowings</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade payables</td>
<td>204.1</td>
<td>160.0</td>
</tr>
<tr>
<td>Other financial liabilities</td>
<td>785.1</td>
<td>818.7</td>
</tr>
<tr>
<td><strong>Total trade payables and other financial liabilities at amortized cost, other than loans and borrowings</strong></td>
<td>€ 989.2</td>
<td>€ 978.7</td>
</tr>
<tr>
<td><strong>Total other financial liabilities</strong></td>
<td>€ 995.3</td>
<td>€ 1,356.5</td>
</tr>
<tr>
<td><strong>Total current</strong></td>
<td>989.2</td>
<td>1,350.4</td>
</tr>
<tr>
<td><strong>Total non-current</strong></td>
<td>6.1</td>
<td>6.1</td>
</tr>
<tr>
<td><strong>Total financial liabilities</strong></td>
<td>€ 1,005.3</td>
<td>€ 1,357.6</td>
</tr>
</tbody>
</table>

(1) The convertible note was fully redeemed by exercising our early redemption option as of March 1, 2022, the redemption date.

### Total Financial Liabilities

<table>
<thead>
<tr>
<th>(in millions)</th>
<th>December 31, 2022</th>
<th>December 31, 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lease liabilities, loans and borrowings</td>
<td>€ 212.2</td>
<td>€ 301.5</td>
</tr>
<tr>
<td>Other financial liabilities</td>
<td>995.3</td>
<td>1,356.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>€ 1,207.5</td>
<td>€ 1,658.0</td>
</tr>
<tr>
<td><strong>Total current</strong></td>
<td>1,025.2</td>
<td>1,480.3</td>
</tr>
<tr>
<td><strong>Total non-current</strong></td>
<td>182.3</td>
<td>177.7</td>
</tr>
</tbody>
</table>

### Loans and Borrowings

**June 2020 Private Placement – Convertible Note**

A fund associated with Temasek (Ellington Investments Pte. Ltd.), or Temasek, and another accredited investor participated in a private investment which we refer to as the June 2020 Private Placement. The private placement included an investment in a four-year mandatory convertible note and in an investment in ordinary shares and closed as of August 28, 2020, following the satisfaction of customary closing conditions. The private placement included an investment in ordinary shares (see Note 15) and a €100.0 million investment in a four-year mandatory convertible note with a coupon of 4.5% per annum and a conversion premium of 20% above its reference price. As of closing, the convertible note had been classified as a financial liability according to IAS 32 because the conversion features of the note lead to a conversion into a variable number of shares and is measured at amortized cost since the fair value option was not applied. On initial recognition, the financial liability was measured at the present value of the contractually determined future cash flows discounted at the effective interest rate of 9.0%. The financial liability was subsequently measured at amortized cost by using the effective interest rate method, reflecting actual and revised estimated contractual cash flows until extinguished upon conversion. In February 2022, we gave notice to Temasek that we would exercise our early redemption option and fully redeemed the convertible note on March 1, 2022, the redemption date. As of the redemption date, the conversion features provided for in the contract initially identified as a combined embedded derivative were finally measured at fair value through profit and loss and recognized as finance income in our consolidated statements of profit or loss. During April 2022, the early redemption was fulfilled by issuing the number of our ordinary shares calculated pursuant to the early redemption provisions of the convertible note (see Note 15), plus paying a fractional share and accrued but unpaid interest up to (but excluding) the redemption date.

F-47
Derivatives Not Designated as Hedging Instruments

Derivatives not designated as hedging instruments relate to foreign exchange forward contracts that were entered into during the years ended December 31, 2022, and 2021, to manage some of our foreign currency exposures. The foreign exchange forward contracts are measured at fair value through profit or loss and are intended to reduce the exposure to foreign currency risk resulting from trade receivables denominated in U.S. dollar.

Other Financial Liabilities at Amortized Cost

Other financial liabilities at amortized cost mainly include obligations derived from license agreements which are being incurred with respect to our COVID-19 vaccine sales in our and the collaboration partners’ territories where we and our partners are using third-party intellectual property. In addition, other financial liabilities at amortized cost comprise obligations from services received but not yet invoiced.

12.3 Fair Values

Fair values of cash and cash equivalents, trade receivables, trade payables and other current financial assets and liabilities approximated their carrying amounts as of December 31, 2022 and December 31, 2021, largely due to the short-term maturities of these instruments.

The fair values of financial instruments measured at fair value were reassessed on a quarterly basis. The money market funds, or MMFs, which are recognized as cash and cash equivalents, are valued using quoted prices on the valuation date in active markets (Level 1). The change in the derivative’s fair value related to the equity investment of Pfizer (see Note 15) was derived from our share price development between contract signing and closing (Level 1). As described above, as of the redemption date, the fair value of the derivative embedded in our convertible note was finally assessed by applying the Cox-Ross-Rubinstein binomial tree model which is based on significant observable inputs (Level 2) and described in further detail in Note 15. The foreign exchange forward contracts are valued using valuation techniques, which employ the use of foreign exchange spot and forward rates (Level 2). The fair values of listed equity investments are measured based on the stock prices of the listed companies (Level 1). The fair values of non-listed equity investments are measured based on observable inputs, e.g., based on multiple analyses (Level 2). The initial fair value of contingent considerations determined at acquisition was based on cash flow projections (unobservable Level 3 input factors) and remained valid since no material changes of the underlying performance criteria have occurred.

12.4 Financial Instruments Risk Management Objectives and Policies

Our financial liabilities comprise lease liabilities, loans and borrowings, trade and other payables as well as hedging liabilities. The main purpose of these financial liabilities is to enable our operations. Our principal financial assets include mainly cash 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 approves 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 like trade and other receivables, cash and cash equivalents as well as financial liabilities like trade payables and other financial liabilities. We do not consider interest risks as well as other price risks as material risks for us.

The sensitivity analysis in the following sections is related to the position as of December 31, 2022 and December 31, 2021.
There were no material changes in the way the risks were managed and valued during the years ended December 31, 2022, and 2021. Because of the significantly higher cash balances the market risk exposure on counterparty risk has increased.

**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 which significantly increased in the past year. 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 as well as expanding our global footprint further. Especially when funds are required in Euros, we are exposed to foreign currency exchange risks. With the aim of preserving capital, surplus liquidity is invested carefully for example into foreign currency investments. 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, a matter of principle, foreign exchange forward contracts are concluded as instruments to mitigate foreign currency exchange risk associated with foreign currency-denominated payments. However, the foreign exchange forward contracts which we entered 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:

<table>
<thead>
<tr>
<th>(in millions)</th>
<th>December 31, 2022</th>
<th>December 31, 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalents in U.S. dollar</td>
<td>€ 1,487.4</td>
<td>€ 436.2</td>
</tr>
<tr>
<td>Monetary assets in U.S. dollar</td>
<td>7,098.5</td>
<td>11,895.5</td>
</tr>
<tr>
<td>Monetary liabilities and provisions in U.S. dollar</td>
<td>1,527.8</td>
<td>656.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>€ 7,058.1</strong></td>
<td><strong>€ 11,675.0</strong></td>
</tr>
</tbody>
</table>

The following tables demonstrate the sensitivity to a reasonably 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.

<table>
<thead>
<tr>
<th>Currency</th>
<th>Change in U.S. dollar rate</th>
<th>Effect on profit (loss) before tax</th>
<th>Effect on pre-tax equity</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. dollar</td>
<td>2022</td>
<td>+5%</td>
<td>€ 195.2</td>
</tr>
<tr>
<td>United States</td>
<td>2021</td>
<td>-5%</td>
<td>215.7</td>
</tr>
<tr>
<td></td>
<td>2022</td>
<td>-5%</td>
<td>325.3</td>
</tr>
<tr>
<td></td>
<td>2021</td>
<td>-5%</td>
<td>364.3</td>
</tr>
</tbody>
</table>

### 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 deposits with banks and financial institutions, foreign exchange transactions and trade and other receivables.
Trade and Other Receivables

Our exposure to credit risks of trade 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 established in connection with fulfilling our commercial obligations in our territories as defined under our current COVID-19 collaboration agreements. 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. The compliance with credit limits by corporate customers is regularly monitored by us.

As of December 31, 2022, the outstanding trade receivables were mainly due from our collaboration partner Pfizer. Besides well-established pharmaceutical companies and governmental institutions, to a smaller extent, our other customers are medical universities, other public institutions and peers in the biopharma industry, which all have very high credit ratings. Due to this customer portfolio, the credit risk on trade receivables is generally very low. We have not incurred bad debt expense and do not expect that this will change with respect to the trade receivables outstanding as of December 31, 2022.

Generally, if overdue by more than 90 days and not subject to enforcement activity, trade receivables are considered for write-offs. The maximum exposure to credit risk at the reporting date is the carrying value of each class of financial assets disclosed in Note 12.2. The expected credit risk on trade receivables and other financial assets derived from applying the simplified approach in calculating expected credit losses was estimated to be not material as of December 31, 2022, and December 31, 2021. We do not hold collateral as security.

Cash and Cash Equivalents as well as Cash Deposits with an Original Term of Three Months and MMFs

Credit risks from balances with banks and financial institutions are managed by our Treasury department in accordance with our investment and asset management policy.

Credit risk stemming from cash and cash equivalents, cash deposits with an original term of three months as well as from MMFs is very low due to its demand feature and the high credit rating of the respective banks.

The maximum exposure to credit risk for the components of the consolidated statements of financial position as of December 31, 2022, and December 31, 2021, are the carrying amounts as illustrated in Note 12.1 and Note 12.2.

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 is 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, as well as by monitoring forecasted and actual cash flows and reconciling the maturity profiles of financial assets and liabilities.

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.
The maturity profile of our financial liabilities based on contractual undiscounted payments is summarized as follows:

### Year ended December 31, 2022

<table>
<thead>
<tr>
<th>Liabilities</th>
<th>Less than 1 year</th>
<th>1 to 5 years</th>
<th>More than 5 years</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loans and borrowings</td>
<td>€ —</td>
<td>€ 2.1</td>
<td>€ —</td>
<td>€ 2.1</td>
</tr>
<tr>
<td>Trade and other payables</td>
<td>€ 204.1</td>
<td>—</td>
<td>—</td>
<td>€ 204.1</td>
</tr>
<tr>
<td>Lease liabilities</td>
<td>€ 40.5</td>
<td>€ 112.9</td>
<td>€ 79.1</td>
<td>€ 232.5</td>
</tr>
<tr>
<td>Contingent consideration</td>
<td>—</td>
<td>—</td>
<td>€ 6.1</td>
<td>€ 6.1</td>
</tr>
<tr>
<td>Other financial liabilities</td>
<td>€ 785.1</td>
<td>—</td>
<td>—</td>
<td>€ 785.1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>€ 1,029.7</strong></td>
<td><strong>€ 115.0</strong></td>
<td><strong>€ 85.2</strong></td>
<td><strong>€ 1,229.9</strong></td>
</tr>
</tbody>
</table>

### Year ended December 31, 2021

<table>
<thead>
<tr>
<th>Liabilities</th>
<th>Less than 1 year</th>
<th>1 to 5 years</th>
<th>More than 5 years</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loans and borrowings</td>
<td>€ 2.6</td>
<td>€ 11.5</td>
<td>€ 6.1</td>
<td>€ 20.2</td>
</tr>
<tr>
<td>Trade and other payables</td>
<td>€ 160.0</td>
<td>—</td>
<td>—</td>
<td>€ 160.0</td>
</tr>
<tr>
<td>Lease liabilities</td>
<td>€ 31.3</td>
<td>€ 89.1</td>
<td>€ 88.9</td>
<td>€ 209.3</td>
</tr>
<tr>
<td>Contingent consideration</td>
<td>—</td>
<td>—</td>
<td>€ 6.1</td>
<td>€ 6.1</td>
</tr>
<tr>
<td>Foreign exchange forward contracts</td>
<td>€ 63.0</td>
<td>—</td>
<td>—</td>
<td>€ 63.0</td>
</tr>
<tr>
<td>Other financial liabilities</td>
<td>€ 818.7</td>
<td>—</td>
<td>—</td>
<td>€ 818.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>€ 1,075.6</strong></td>
<td><strong>€ 100.6</strong></td>
<td><strong>€ 101.1</strong></td>
<td><strong>€ 1,277.3</strong></td>
</tr>
</tbody>
</table>

#### 12.8 Changes in Liabilities Arising from Financing Activities

<table>
<thead>
<tr>
<th>Liabilities</th>
<th>January 1, 2022</th>
<th>Cash flows</th>
<th>Acquisition of subsidiaries and businesses</th>
<th>Changes in fair value</th>
<th>New leases and disposals</th>
<th>Reclassification</th>
<th>Other</th>
<th>December 31, 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current obligations under lease contracts</td>
<td>€ 21.7</td>
<td>€ (41.7)</td>
<td>€ —</td>
<td>€ —</td>
<td>€ 12.5</td>
<td>€ 33.5</td>
<td>€ 1.1</td>
<td>€ 56.8</td>
</tr>
<tr>
<td>Non-current obligations under lease contracts</td>
<td>155.7</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(33.3)</td>
<td>1.1</td>
<td>174.1</td>
</tr>
<tr>
<td>Loans and borrowings</td>
<td>119.9</td>
<td>(18.0)</td>
<td>—</td>
<td>—</td>
<td>— (99.8)</td>
<td>—</td>
<td>—</td>
<td>2.1</td>
</tr>
<tr>
<td>Convertible note – embedded derivative</td>
<td>308.7</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>— (308.7)</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>€ 612.2</strong></td>
<td><strong>€ (159.1)</strong></td>
<td><strong>€ —</strong></td>
<td><strong>€ —</strong></td>
<td><strong>€ (67.4)</strong></td>
<td><strong>€ (36.3)</strong></td>
<td><strong>€ —</strong></td>
<td><strong>212.2</strong></td>
</tr>
</tbody>
</table>

(1) Related to the early redemption of our convertible note during the year ended December 31, 2022, as further described in Note 15.
13 Inventories

During the year ended December 31, 2022, inventory write-offs to net realizable value and reserves related to our COVID-19 vaccine amounting to €484.6 million were recognized in cost of sales due to the switch from the BNT162b2 vaccine to an Omicron-adapted bivalent vaccine and further raw materials reserves recognized with respect to our excess stock, compared to €194.6 million in the previous period. The inventories valued at net realizable value in our consolidated statements of financial position as of December 31, 2022, consider contractual compensation payments. We have not pledged any inventories as securities for liabilities. During the years ended December 31, 2022, and 2021, costs of inventories in the amount of €1,550.6 million and €1,255.1 million, respectively, were recognized as cost of sales.

14 Other Non-Financial Assets

Issued Capital and Reserves

As of December 31, 2022, the number of shares outstanding was 243,215,169. This amount excludes 5,337,031 shares held in treasury. For the year ended December 31, 2021, the number of shares outstanding was 242,521,489, excluding 3,788,592 shares held in treasury.

F-52
Second Tranche Share Repurchase Program

In November 2022, our Management Board and Supervisory Board authorized the second tranche of our share repurchase program of ADSs, with a value of up to $0.5 billion, commencing on December 7, 2022.

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 a potential 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 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 March 2022, our Management Board and Supervisory Board authorized a share repurchase program of ADSs, pursuant to which we may repurchase ADSs in the amount of up to $1.5 billion over the next two years. On May 2, 2022, the first tranche of our share repurchase program of ADSs, with a value of up to $1.0 billion, commenced. In November 2022, our Management Board and Supervisory Board authorized the second tranche of our share repurchase program of ADSs, with a value of up to $0.5 billion, commencing on December 7, 2022. During the year ended December 31, 2022, ADSs were repurchased at an average price of $143.98, for total consideration of $1.0 billion (€986.4 million). Repurchased ADSs were used to satisfy settlement obligations under our share-based payment arrangements.

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).

Capital Transactions During the Year Ended December 31, 2021

In November 2020, we entered into a sales agreement, or the Sales Agreement, with Jefferies LLC and SVB Leerink LLC (now known 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, 2021, 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 ADSs during the year ended December 31, 2022. As of December 31, 2022, the remaining capacity under the Sales Agreement is still $207.1 million. Under the at-the-market offering program ADSs are sold via the stock exchange and therefore no shareholders’ subscription rights are affected. As a result of the transaction, treasury shares in the amount of €1.0 million were issued and the capital reserve increased by €162.6 million during the year ended December 31, 2021. Costs of €2.7 million related to the equity transaction were recorded in equity as deduction from the capital reserve.
During the years ended December 31, 2022, 2021, and 2020, our share-based payment arrangements led to the following expenses:

<table>
<thead>
<tr>
<th>Years ended</th>
<th>€ millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 31</td>
<td>2022</td>
</tr>
<tr>
<td>Expense arising from equity-settled share-based payment arrangements</td>
<td>€46.5</td>
</tr>
<tr>
<td>Employee Stock Ownership Plan</td>
<td>16.5</td>
</tr>
<tr>
<td>Chief Executive Officer Grant</td>
<td>16.4</td>
</tr>
<tr>
<td>Management Board Grant(1)</td>
<td>16.3</td>
</tr>
<tr>
<td>BioNTech 2020 Employee Equity Plan for Employees Based Outside North America</td>
<td>16.1</td>
</tr>
<tr>
<td>Expense arising from cash-settled share-based payment arrangements</td>
<td>61.5</td>
</tr>
<tr>
<td>Employee Stock Ownership Plan</td>
<td>16.5</td>
</tr>
<tr>
<td>Management Board Grant(1)</td>
<td>16.3</td>
</tr>
<tr>
<td>BioNTech Restricted Stock Unit Plan for North America Employees</td>
<td>16.1</td>
</tr>
<tr>
<td>Total</td>
<td>€108.0</td>
</tr>
</tbody>
</table>

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 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 20.2).

During the years ended December 31, 2022, 2021, and 2020, our share-based payment arrangements led to a cash outflow of €51.8 million, €13.4 million and nil million, respectively. We expect to settle equity-settled share-based payment arrangements under the Chief Executive Officer Grant (see Note 16.4) and under 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. If all of the rights outstanding as of December 31, 2022, will be exercised accordingly, the cash outflow to the tax authority in 2023 would amount to approximately €360.0 million (based on the share price as of December 31, 2022).

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. As of the grant date in February 2021, the European Plan was implemented for the calendar year 2020 by entering into
award agreements with our employees under the LTI 2020 program. In addition, further award agreements were entered into under the LTI-plus program with employees who did not participate in the Employee Stock Ownership Plan, or ESOP. In January 2022 and December 2022, the European Plan was granted for the calendar years 2021 and 2022, respectively. 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 grant date.

<table>
<thead>
<tr>
<th>Reconciliation of Outstanding Share-Options</th>
<th>LTI-plus program</th>
<th>LTI 2020 program</th>
<th>LTI 2021 program</th>
<th>LTI 2022 program</th>
</tr>
</thead>
<tbody>
<tr>
<td>As of January 1, 2021</td>
<td>398,938</td>
<td>252,766</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Granted / Allocated</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(24,927)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forfeited / Modified</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(10,350)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>As of December 31, 2021</td>
<td>372,011</td>
<td>242,416</td>
<td>110,036</td>
<td></td>
</tr>
<tr>
<td>As of January 1, 2022</td>
<td>372,011</td>
<td>242,416</td>
<td>110,036</td>
<td></td>
</tr>
<tr>
<td>Forfeited / Modified</td>
<td>(7,932)</td>
<td>(7,111)</td>
<td>(5,428)</td>
<td></td>
</tr>
<tr>
<td>Granted / Allocated</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>396,110</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercised(1)</td>
<td>(364,079)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>As of December 31, 2022</td>
<td>24,032</td>
<td>104,608</td>
<td>396,110</td>
<td></td>
</tr>
<tr>
<td>thereof vested</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>thereof un-vested</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(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

<table>
<thead>
<tr>
<th>Inputs Used in Measurement of the Fair Values at Grant Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>LTI-plus program</td>
</tr>
<tr>
<td>------------------</td>
</tr>
<tr>
<td>Weighted average fair value</td>
</tr>
<tr>
<td>Waiting period (in years)</td>
</tr>
</tbody>
</table>

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, 2022, and 2021, 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, 2022, 2021, and 2020, the exercise of RSUs resulted in a cash outflow of €9.4 million, €10.1 million and nil million, respectively.
As of December 31, 2022, the liability related to these awards amounted to €13.4 million (€13.0 million as of December 31, 2021).

16.2 Management Board Grant – Short-Term Incentive (Cash-Settled)

The service agreements with our Management Board provide for a short-term incentive compensation 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 instalments 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., being the service commencement date, until each separate determination date and are remeasured until settlement date. As of December 31, 2022, the liability related to these awards amounted to €2.3 million (€1.0 million as of December 31, 2021).

16.3 Management Board Grant Long-Term Incentive (Partly Equity-Settled, Partly Cash-Settled)

Description of Share-Based Payments

The service agreements with our Management Board 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 will be 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 agreement thereunder.

The options will vest annually in equal installments over four years commencing on the first anniversary of the allocation date and will be 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, phantom options equivalent to the number of options the Management Board members would have been entitled to receive for 2021 and 2022 were granted under the Management Board Grant 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. As of December 31, 2022, the assessment of options expected to be allocated in future years was based on estimated allocation dates in the middle of the respective years.
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:

<table>
<thead>
<tr>
<th>Allocation date</th>
<th>February 2020</th>
<th>Allocation date</th>
<th>May 12, 2021</th>
<th>Allocation date</th>
<th>May 17, 2021</th>
<th>Allocation date</th>
<th>May 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weighted average fair value</td>
<td>€ 10.83</td>
<td>€ 54.51</td>
<td>€ 56.69</td>
<td>€ 65.99</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weighted average share price</td>
<td>€ 28.20</td>
<td>€ 174.51</td>
<td>€ 185.92</td>
<td>€ 153.16</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise price(1)</td>
<td>€ 28.32</td>
<td>€ 173.66</td>
<td>€ 175.16</td>
<td>€ 142.60</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expected volatility (%)</td>
<td>36.6%</td>
<td>46.5%</td>
<td>46.5%</td>
<td>44.4%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expected life (years)</td>
<td>4.8</td>
<td>4.6</td>
<td>4.6</td>
<td>5.8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk-free interest rate (%)</td>
<td>1.6%</td>
<td>3.8%</td>
<td>3.8%</td>
<td>3.9%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(1) Classified as cash-settled share-based payment arrangement; all other share-based payment arrangements are classified as equity-settled.

For the awards allocated as of February 2020, the exercise price for each option is $30.78 (€28.32), calculated using the foreign exchange rate published by the German Central Bank (Deutsche Bundesbank) as of the grant date. The share options allocated as of February 2020 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. Our Supervisory Board reserves the right to limit the economic benefit from the exercise of the options to extent the result from extraordinary events or developments. For the awards allocated as of May 12, 2021, May 17, 2021, and May 31, 2022 the exercise prices are $185.23 (€173.66), $186.83 (€175.16) and $152.10 (€142.60), respectively (all amounts calculated as of December 31, 2022, using the foreign exchange rate as published by the German Central Bank (Deutsche Bundesbank)). 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. The phantom share options allocated as of May 2021 and 2022 are subject to the effective exercise price cap. In addition, the maximum compensation that the Management Board members are entitled to receive under those relevant agreements together with other compensation components received by each such board member in the respective grant year is capped at €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, 2022, are presented in the table below.

<table>
<thead>
<tr>
<th>Allocation date</th>
<th>Allocation date</th>
<th>Allocation date</th>
<th>Allocation date</th>
</tr>
</thead>
<tbody>
<tr>
<td>February 2020</td>
<td>2020</td>
<td>May 12, 2021</td>
<td>6,463</td>
</tr>
<tr>
<td>May 17, 2021</td>
<td>86,118</td>
<td>May 2022</td>
<td></td>
</tr>
</tbody>
</table>

(Phantom) share options outstanding (expected to be allocated)

<table>
<thead>
<tr>
<th>Allocation date</th>
<th>Estimated allocation date</th>
<th>Estimated allocation date</th>
<th>Estimated allocation date</th>
<th>Estimated allocation date</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 12, 2021</td>
<td>2020</td>
<td>2021</td>
<td>2022</td>
<td>2023</td>
</tr>
<tr>
<td>(Phantom) share options outstanding (expected to be allocated)</td>
<td>97,436</td>
<td>93,785</td>
<td>63,251</td>
<td>48,705</td>
</tr>
</tbody>
</table>

Weighted average exercise price (€)

<table>
<thead>
<tr>
<th>Estimated allocation date</th>
<th>Estimated allocation date</th>
<th>Estimated allocation date</th>
<th>Estimated allocation date</th>
</tr>
</thead>
<tbody>
<tr>
<td>February 2020</td>
<td>2020</td>
<td>May 12, 2021</td>
<td>6,463</td>
</tr>
<tr>
<td>May 17, 2021</td>
<td>86,118</td>
<td>May 2022</td>
<td>142.60</td>
</tr>
</tbody>
</table>

(1) Classified as cash-settled share-based payment arrangement; all other share-based payment arrangements are classified as equity-settled.

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, 2022, 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 4.0 years (as of December 31, 2021: 3.6 years).

As of December 31, 2022, the liability related to the phantom option awards amounted to €5.6 million (€3.2 million as of December 31, 2021).

16.4 Chief Executive Officer Grant (Equity-Settled)

Description of Share-Based Payments

In September 2019, we granted Prof. Ugur Sahin, M.D., an option to purchase 4,374,963 of our ordinary shares, subject to Prof. 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. As a result, the effective exercise price will not increase above 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 will be exercisable 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, 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 grant the date. The inputs used in the measurement of the fair value at grant the date of the Chief Executive Officer Grant were as follows:

<table>
<thead>
<tr>
<th>Grant Date: October 9, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Weighted average fair value</strong></td>
</tr>
<tr>
<td><strong>Weighted average share price</strong></td>
</tr>
<tr>
<td><strong>Exercise price</strong></td>
</tr>
<tr>
<td><strong>Expected volatility (%)</strong></td>
</tr>
<tr>
<td><strong>Expected life (years)</strong></td>
</tr>
<tr>
<td><strong>Risk-free interest rate (%)</strong></td>
</tr>
</tbody>
</table>

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

During the years ended December 31, 2022, and 2021, no further options were granted or forfeited. As of December 31, 2022, 75% of the options have vested but are subject to waiting requirements.

As of December 31, 2022, the share options outstanding had a remaining weighted average expected life of 2.1 years (as of December 31, 2021: 3.1 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 the participants a certain number of rights by explicit acceptance by the participants. The exercise of the 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, other than Ryan Richardson, who was not a Management Board member at the time the options were granted, the options are subject to the effective exercise price cap as well as 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. As a result, the effective exercise price will not increase above a Euro amount equivalent to $30.00. The option rights (other than Prof. Özlem Türeci’s, M.D., and Ryan Richardson’s options) generally fully vest after four years and can only 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. Also, 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:

<table>
<thead>
<tr>
<th>Grant date</th>
<th>November 15, 2018</th>
<th>Grant dates between February 21 and April 3, 2019</th>
<th>Grant dates between April 29 and May 31, 2019</th>
<th>Grant date December 1, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weighted average fair value</td>
<td>€7.41</td>
<td>€6.93</td>
<td>€7.04</td>
<td>€9.47</td>
</tr>
<tr>
<td>Weighted average share price</td>
<td>€14.40</td>
<td>€15.72</td>
<td>€16.03</td>
<td>€19.44</td>
</tr>
<tr>
<td>Exercise price (1)</td>
<td>€10.14</td>
<td>€15.03</td>
<td>€15.39</td>
<td>€15.82</td>
</tr>
<tr>
<td>Expected volatility (%)</td>
<td>46.0%</td>
<td>46.0%</td>
<td>46.0%</td>
<td>46.0%</td>
</tr>
<tr>
<td>Expected life (years)</td>
<td>5.8</td>
<td>6.0</td>
<td>6.0</td>
<td>5.5</td>
</tr>
<tr>
<td>Risk-free interest rate (%)</td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.1%</td>
</tr>
</tbody>
</table>

(1) With respect to the Management Board members, other than Ryan Richardson who was not a Management Board member 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:

<table>
<thead>
<tr>
<th>Period</th>
<th>Share options outstanding</th>
<th>Number of ordinary shares underlying options</th>
<th>Weighted average exercise price</th>
</tr>
</thead>
<tbody>
<tr>
<td>As of January 1, 2021</td>
<td>645,892</td>
<td>11,626,056</td>
<td>10.23</td>
</tr>
<tr>
<td>Forfeited</td>
<td>(3,885)</td>
<td>(69,932)</td>
<td>10.14</td>
</tr>
<tr>
<td>As of December 31, 2021</td>
<td>642,007</td>
<td>11,556,124</td>
<td>10.23</td>
</tr>
<tr>
<td>As of January 1, 2022</td>
<td>642,007</td>
<td>11,556,124</td>
<td>10.23</td>
</tr>
<tr>
<td>Modified</td>
<td>(1,040)</td>
<td>(18,720)</td>
<td>10.14</td>
</tr>
<tr>
<td>Exercised</td>
<td>(583,383)</td>
<td>(10,500,890)</td>
<td>10.14</td>
</tr>
<tr>
<td>As of December 31, 2022</td>
<td>57,584</td>
<td>1,036,514</td>
<td>11.16</td>
</tr>
<tr>
<td>thereof vested</td>
<td>48,331</td>
<td>869,960</td>
<td>10.14</td>
</tr>
<tr>
<td>thereof un-vested</td>
<td>9,253</td>
<td>166,554</td>
<td>15.29</td>
</tr>
</tbody>
</table>

(1) With respect to the Management Board members, other than Ryan Richardson who was not a Management Board member 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 settlement dates converted from USD to Euro using the exchange rate published by the German Central Bank (Deutsche Bundesbank) on the same days was €160.44.

The Supervisory Board determined in September 2022 that the ESOP settlement in November and December 2022 would be made by delivery of 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 respective number of ADSs was settled with treasury shares. 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 neither change the rights as such nor did it change the classification as equity-settled option rights.

As of December 31, 2022, the share options outstanding under our equity-settled share-based payment arrangements had a remaining weighted average expected life of 1.8 years (as of December 31, 2021: 2.7 years).

Development of Share-Options (Cash-Settled)

During the year ended December 31, 2022, 343,854 phantom options were granted under the ESOP which each gives 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. Generally, the options’ exercise prices are €10.14. Contemporaneous with the exercise of the equity-based option rights in November and December 2022, 289,168 cash-settled phantom option rights were exercised and resulted in a cash outflow of €42.2 million. 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 €155.39. As of December 31, 2022, 131,853 cash-settled option rights remained outstanding. As of December 31, 2022, the liability related to cash-settled share-based payment option rights under the ESOP program amounted to €34.5 million (€11.2 million as of December 31, 2021), of which €11.2 million (nil as of December 31, 2021) 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.
As of December 31, 2022, our current provisions included €235.5 million (nil as of December 31, 2021) of obligations for production capacities derived from contracts with Contract Manufacturing Organizations, or CMOs, that became redundant as a direct result of the introduction of a new COVID-19 vaccine formulation, the switch from the BNT162b2 vaccine to an Omicron-adapted bivalent vaccine and due to increased internal manufacturing capacities during the year ended December 31, 2022. The related expenses were recognized in cost of sales in our consolidated statements of profit or loss. The change of €235.5 million compared to the previous period related to additions.

Provisions for legal proceedings mainly related to purported obligations arising out of certain contractual disputes unrelated to the below mentioned patent proceedings (€177.9 million as of December 31, 2021), were mainly released due to the favorable outcome of such proceeding received in March 2023 and treated as an adjusting event (as of September 30, 2022 our provisions for legal proceedings amounted to €359.1 million).

As of December 31, 2022, our current provisions included €140.2 million in other obligations mainly comprising inventor remunerations as well as customs and duties (€117.2 million as of December 31, 2021, mainly comprising inventor remunerations as well as customs and duties). The change of €23.0 million compared to the previous period related mainly to additions.

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, 2022, 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, 2022, 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

### Provisions

<table>
<thead>
<tr>
<th>(in millions)</th>
<th>December 31, 2022</th>
<th>December 31, 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obligations from onerous CMO contracts</td>
<td>€235.5</td>
<td>—</td>
</tr>
<tr>
<td>Legal proceedings</td>
<td>0.1</td>
<td>177.9</td>
</tr>
<tr>
<td>Other</td>
<td>140.2</td>
<td>117.2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>€375.8</strong></td>
<td><strong>€295.1</strong></td>
</tr>
<tr>
<td>Total current</td>
<td>367.2</td>
<td>110.2</td>
</tr>
<tr>
<td>Total non-current</td>
<td>8.6</td>
<td>184.9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Provisions as of December 31, 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obligations from onerous CMO contracts</td>
</tr>
<tr>
<td>Legal proceedings</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
<tr>
<td><strong>Total current</strong></td>
</tr>
<tr>
<td><strong>Total non-current</strong></td>
</tr>
</tbody>
</table>
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 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.

**CureVac Proceedings**

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, DE202015009741U1, and DE20201005375U1. Later 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 August 2022, CureVac added European Patent EP3708668B1, or the EP'668 Patent, to its German lawsuit. 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 addition, we filed a nullity action in the Federal Patent Court of Germany seeking a declaration that the EP'122 Patent is invalid. Lastly, on November 11, 2022, we filed cancellation actions seeking the cancellation of the three German Utility Models in the German Patent and Trademark Office. All of the 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 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.

**Moderna Proceedings**

In August 2022, ModernaTX, Inc., or Moderna, filed three patent infringement lawsuits against us and Pfizer related to Comirnaty. 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. Moderna filed a second lawsuit

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.

<table>
<thead>
<tr>
<th>Other Non-Financial Liabilities</th>
<th>December 31, 2022</th>
<th>December 31, 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liabilities from wage taxes and social security expenses</td>
<td>€ 761.8</td>
<td>€ 3.8</td>
</tr>
<tr>
<td>Liabilities to employees</td>
<td>50.6</td>
<td>10.2</td>
</tr>
<tr>
<td>Liabilities from share-based payment arrangements</td>
<td>36.2</td>
<td>20.6</td>
</tr>
<tr>
<td>Other</td>
<td>29.2</td>
<td>4.3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>€ 877.8</strong></td>
<td><strong>€ 58.9</strong></td>
</tr>
<tr>
<td><strong>Total current</strong></td>
<td><strong>860.8</strong></td>
<td><strong>46.1</strong></td>
</tr>
<tr>
<td><strong>Total non-current</strong></td>
<td><strong>17.0</strong></td>
<td><strong>12.8</strong></td>
</tr>
</tbody>
</table>

Liabilities from wage taxes and social security expenses mainly include obligations that became due upon settlement of our share-based payment arrangements for the respective employees and members of the Management Board as further described in Note 16.
19 Leases

19.1 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:

<table>
<thead>
<tr>
<th>(in millions)</th>
<th>December 31, 2022</th>
<th>December 31, 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buildings</td>
<td>€206.5</td>
<td>€175.0</td>
</tr>
<tr>
<td>Production facilities</td>
<td>3.0</td>
<td>19.4</td>
</tr>
<tr>
<td>Other operating equipment</td>
<td>2.4</td>
<td>3.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>€211.9</strong></td>
<td><strong>€197.9</strong></td>
</tr>
</tbody>
</table>

Additions to the right-of-use assets during the year ended December 31, 2022, were €118.3 million (during the year ended December 31, 2021: €126.5 million).

Lease Liability

The following amounts are included in loans and borrowings as of the dates indicated:

<table>
<thead>
<tr>
<th>(in millions)</th>
<th>December 31, 2022</th>
<th>December 31, 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>€36.0</td>
<td>€27.9</td>
</tr>
<tr>
<td>Non-current</td>
<td>174.1</td>
<td>153.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>€210.1</strong></td>
<td><strong>€181.6</strong></td>
</tr>
</tbody>
</table>

19.2 Amounts Recognized in the Consolidated Statements of Profit or Loss

Depreciation Charge of Right-of-Use Assets

<table>
<thead>
<tr>
<th>(in millions)</th>
<th>2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buildings</td>
<td>€35.2</td>
<td>€14.7</td>
<td>€4.7</td>
</tr>
<tr>
<td>Production facilities</td>
<td>23.1</td>
<td>14.0</td>
<td>1.6</td>
</tr>
<tr>
<td>Other operating equipment</td>
<td>0.5</td>
<td>0.3</td>
<td>—</td>
</tr>
<tr>
<td>Total depreciation charge</td>
<td><strong>€58.8</strong></td>
<td><strong>€29.0</strong></td>
<td><strong>€6.3</strong></td>
</tr>
<tr>
<td>Interest on lease liabilities</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Expense related to short-term leases and leases of low-value assets</td>
<td>27.1</td>
<td>9.5</td>
<td>1.2</td>
</tr>
<tr>
<td><strong>Total amounts recognized in profit or loss</strong></td>
<td><strong>€91.0</strong></td>
<td><strong>€41.4</strong></td>
<td><strong>€9.5</strong></td>
</tr>
</tbody>
</table>

19.3 Amounts Recognized in the Consolidated Statements of Cash Flows

During the year ended December 31, 2022, the total cash outflow for leases amounted to €46.2 million (during the year ended December 31, 2021: €17.0 million; during the year ended December 31, 2020: €14.7 million).

19.4 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 judgement 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 €163.1 million as of December 31, 2022, considering terms up until 2049 (as of December 31, 2021: €82.8 million considering terms up until 2049).

20 Related Party Disclosures

20.1 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 enabled it to exercise the majority of voting rights to pass resolutions at our Annual General Meeting, or AGM. Entities controlled by ATHOS KG mainly provide rental and property management activities and sell property, plant and equipment to us.

20.2 Transactions with Key Management Personnel

In June 2022, at the Annual General Meeting, our shareholders voted to reappoint Helmut Jeggle as a member of the Supervisory Board and appointed two additional Supervisory Board members, Prof. Dr. Anja Morawietz and Prof. Dr. Rudolf Staudigl. In a meeting following the AGM, the Supervisory Board re-elected Helmut Jeggle as its Chair. All three members will serve in their roles until the 2026 AGM.

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:

<table>
<thead>
<tr>
<th>(in millions)</th>
<th>Years ended December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2022</td>
</tr>
<tr>
<td>Management Board</td>
<td></td>
</tr>
<tr>
<td>Fixed compensation</td>
<td>2.9</td>
</tr>
<tr>
<td>Short-term incentive – first installment</td>
<td>0.6</td>
</tr>
<tr>
<td>Short-term incentive – second installment(1)</td>
<td>0.7</td>
</tr>
<tr>
<td>Other performance-related variable compensation(1)</td>
<td>0.1</td>
</tr>
<tr>
<td>Share-based payments (incl. long-term incentive)(3)</td>
<td>10.7</td>
</tr>
<tr>
<td>Supervisory Board</td>
<td>8.5</td>
</tr>
<tr>
<td>Total compensation paid to key management personnel</td>
<td>15.5</td>
</tr>
</tbody>
</table>

(1) The fair value of the second installment of the short-term incentive compensation which has been classified as 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 “Share-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, 2022, and 2021, the amounts included expenses derived from a one-time signing bonus of €800,000 granted to Jens Holstein as of his appointment to the Management Board by awarding 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 closing price applied when the award was initially granted. In addition, the total cash payment under the award shall not exceed €6.4 million. During the year ended December 31, 2020, the amount included expenses from a bonus arrangement agreed with Ryan Richardson in advance of his appointment to the Management Board. During the year ended December 31, 2020, the arrangement was modified from an all-equity share-based payment arrangement into a partly cash- and partly equity-settled share-based payment arrangement including 4,534 ordinary shares which were issued during the year ended December 31, 2021. Management Board members participate in our ESOP program (see Note 16).
During the year ended December 31, 2022, 5,152,410 option rights granted to our Management Board under the ESOP 2018 program vested and became exercisable (option rights allocated to Ryan Richardson and Özlem Türeci had already vested in 2019 but continued to be subject to performance and waiting requirements; Jens Holstein did not participate in the ESOP 2018 program as he had not joined our company at the time it was allocated). Of such vested option rights, 4,921,630 options were exercised during the year ended December 31, 2022 by paying the option exercise price of €19.78 weighted over the Management Board members (for all Management Board members, apart from Ryan Richardson who was not a Management Board member at the time the option rights were allocated, exercise prices are subject the effective exercise price cap and the maximum cap mechanism as described in Note 16.5). As of December 31, 2022, Sean Marett still holds 230,780 option rights which can only be exercised during the exercise windows as defined by our ESOP and if certain performance conditions are fulfilled as of the date the relevant option rights are exercised. The average closing price of an American Depositary Share of BioNTech on Nasdaq weighted over the Management Board’s settlement dates converted from USD to Euro using the exchange rate published by the German Central Bank (Deutsche Bundesbank) on the same days was €160.65.

Key Management Personnel Transactions

A number of key management personnel, or their related parties, hold positions in other companies that result in them having control or significant influence over these companies. A number of these companies have entered into transactions with us during the year.

We purchased various goods and services from Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg-Universität Mainz gemeinnützige GmbH, or TRON.

The aggregate value of transactions related to key management personnel was as follows for the periods indicated:

<table>
<thead>
<tr>
<th>Years ended December 31,</th>
<th>2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchases of various goods and services from TRON</td>
<td>€—</td>
<td>€—</td>
<td>€10.1</td>
</tr>
<tr>
<td>Total</td>
<td>€—</td>
<td>€—</td>
<td>€10.1</td>
</tr>
</tbody>
</table>

(1) We purchased various goods and services from TRON, an institute where Prof. Ugur Sahin, M.D., served as Managing Director. TRON is no longer considered to be a related party for the years ended December 31, 2022, and 2021, as the criteria for such classification are no longer fulfilled.

20.3 Related Party Transactions

The total amount of transactions with ATHOS KG or entities controlled by it was as follows for the periods indicated:

<table>
<thead>
<tr>
<th>Years ended December 31,</th>
<th>2022</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchases of various goods and services from entities controlled by ATHOS KG</td>
<td>€0.3</td>
<td>€0.9</td>
<td>€2.3</td>
</tr>
<tr>
<td>Purchases of property and other assets from entities controlled by ATHOS KG</td>
<td>62.5</td>
<td>—</td>
<td>2.3</td>
</tr>
<tr>
<td>Total</td>
<td>€62.8</td>
<td>€0.9</td>
<td>€4.6</td>
</tr>
</tbody>
</table>

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.

F-67
The outstanding balances of transactions with ATHOS KG or entities controlled by them were as follows as of the periods indicated:

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2022</th>
<th>December 31, 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATHOS KG</td>
<td>€—</td>
<td>€0.3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>€—</td>
<td>€0.3</td>
</tr>
</tbody>
</table>

None of the balances are secured and no bad debt expense has been recognized in respect of amounts owed by related parties.

21 Events After the Reporting Period

Acquisition of InstaDeep Ltd.

On January 10, 2023, we and InstaDeep Ltd., or InstaDeep, a leading global technology company in the field of artificial intelligence (“AI”) and machine learning (“ML”), announced that we have entered a share purchase agreement, or SPA, under which we will acquire 100% of the remaining shares in InstaDeep, excluding the shares already owned by us (see Note 12.2). InstaDeep will operate as our 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 planned to enable the creation of a fully integrated, enterprise-wide capability that leverages AI and machine learning technologies across our therapeutic platforms and operations.

The completion of the acquisition is conditional on the satisfaction of several customary closing conditions and regulatory approvals as defined in the SPA. The acquisition of InstaDeep is expected to close in the first half of 2023 and will be accounted for as a business combination using the acquisition method of accounting.

The transaction includes a total upfront consideration of approximately £362 million (€413.4 million) in cash and our shares to acquire 100% of the remaining InstaDeep shares. Therefore, the final upfront proportion of cash payments and shares and on the development of our share price. In addition, InstaDeep shareholders will be eligible to receive additional performance-based future milestone payments up to approximately £200 million (€228.4 million, both amounts in British pound translated into Euro, using the foreign exchange rate as published by the German Central Bank (Deutsche Bundesbank) as of March 20, 2023).

Strategic collaboration with OncoC4, Inc.

On March 20, 2023, we and OncoC4, Inc., or OncoC4, a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel biologicals for cancer treatment, announced a strategic collaboration to co-develop and commercialize novel checkpoint antibody for the treatment of cancer. Under the terms of the agreement, we receive an exclusive worldwide license for development and commercialization of OncoC4’s anti-CTLA-4 monoclonal antibody candidate, ONC-392. OncoC4 will receive a $200 million (€186.6 million, the amount in U.S. dollar is translated into Euro using the foreign exchange rate as published by the German Central Bank (Deutsche Bundesbank) as of March 20, 2023) upfront payment and is eligible to receive development, regulatory and commercial milestone payments as well as tiered royalties. Together with OncoC4 we will jointly develop ONC-392 as monotherapy and in combination therapy with anti-PD1 in various solid tumor indications and will equally share development costs for such studies. The transaction is expected to be closed in the first half of 2023, subject to customary closing conditions and regulatory clearances.

Second Tranche Share Repurchase Program

Between January 1, and up until March 17, 2023, the date when the trading plan for the second tranche of our share repurchase program expired, the following repurchases under the program have occurred.

### Second Tranche ($0.5 billion)

<table>
<thead>
<tr>
<th>Period</th>
<th>Number of ADSs purchased</th>
<th>Average price paid per ADS</th>
<th>Total number of ADSs purchased</th>
<th>Approximate value of ADSs that may yet be purchased (in millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2022(1)</td>
<td>618,355</td>
<td>$142.26 (€131.12)</td>
<td>618,355</td>
<td>$89.0 (€81.9)</td>
</tr>
<tr>
<td>January 2023</td>
<td>618,355</td>
<td>$142.26 (€131.12)</td>
<td>618,355</td>
<td>412.0 (€418.9)</td>
</tr>
<tr>
<td>February 2023</td>
<td>857,620</td>
<td>$138.05 (€129.06)</td>
<td>1,475,975</td>
<td>$293.6 (€288.2)</td>
</tr>
<tr>
<td>March 2023(2)</td>
<td>745,196</td>
<td>$128.49 (€121.08)</td>
<td>2,221,171</td>
<td>197.9 (€218.6)</td>
</tr>
</tbody>
</table>

F-68
ARTICLES OF ASSOCIATION OF BIONTECH SE

I. General Provisions

§ 1 Company Name, Registered Office and Financial Year

(1) The name of the Company is “BioNTech SE”.
(2) The Company has its registered office in Mainz, Germany.
(3) The financial year is the calendar year.

§ 2 Purpose of Enterprise

(1) The purpose of the Company is the research and development, 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.
(2) The Company may undertake all transactions and actions that are expedient for serving the Company’s purpose. It is also authorized to establish and acquire other companies and to invest in other companies, as well as to manage such companies or to limit itself to the administration of the investment.

§ 3 Announcements

All of the Company’s announcements shall be made exclusively in the German Federal Gazette (Bundesanzeiger).

II. Share Capital and Shares

§ 4 Amount and Division of Share Capital; Deviating Profit Participation

(1) The Company’s share capital totals EUR 248,552,200 and is divided into 248,552,200 no-par value shares.
(2) Any right of the shareholders to request that share certificates be issued is excluded, to the extent permitted by law or unless certification is required under applicable stock exchange rules where the shares or rights or certificates representing them are admitted for trading. Global certificates for shares may be issued. Form and content of these certificates shall be determined by the Management Board.
(3) The shares are registered shares.
(4) In the event of a capital increase, the profit participation of new shares may be determined in deviation from section 66(2) sentence 3 German Stock Corporation Act (AktG).
The Management Board is authorized, with the approval of the Supervisory Board, to increase the Company’s share capital on one or more occasions on or before June 21, 2026 by up to a total of EUR 122,657,313 by issuing up to 122,657,313 new no-par value registered shares in return for cash contributions or contributions in kind (Authorized Capital 2021). Shareholders are in principle to be granted subscription rights. In this context, the shares may also be underwritten by one or more credit institution(s) or one or more company(ies) operating in accordance with Sec. 53 para. 1 sentence 1 or section 53b para. 1 sentence 1 or para. 7 of the German Banking Act (Kreditwesengesetz—KWG) with the obligation to offer them for subscription to the Company’s shareholders (so-called indirect subscription right). The Management Board is authorized, with the approval of the Supervisory Board, to exclude shareholders’ subscription rights for one or more capital increases under the Authorized Capital

(a) to exclude fractional amounts from the subscription right;
(b) in the case of a capital increase against cash contributions, if the issue price of the new shares is not significantly lower than the stock market price of the Company’s shares already listed at the time the issue price is finally fixed. However, this authorization shall only apply subject to the provision that the shares issued with exclusion of subscription rights pursuant to Sec. 186 para. 3 sentence 4 AktG may not exceed a total of 10% of the capital stock either at the time this authorization takes effect or—if this amount is lower—at the time this authorization is exercised. Shares issued or sold in direct or corresponding application of Sec. 186 para. 3 sentence 4 AktG during the term of this authorization until the time of its utilization shall be counted towards this limit of 10% of the share capital. Shares used to service bonds with conversion or option rights or conversion obligations shall be counted towards the 10% limit if these bonds were issued during the authorization period under exclusion of shareholders’ subscription rights in accordance with Sec. 186 para. 3 sentence 4 AktG. Treasury shares which may have been sold by the Company during the term of this authorization under exclusion of subscription rights pursuant to or in accordance with Sec. 186 para. 3 sentence 4 AktG shall be counted towards the 10% limit;
(c) in the event of a capital increase against contributions in kind, in particular in order to be able to offer the new shares to third parties in connection with the acquisition of companies, parts of companies or interests in companies, or license or intellectual property rights;
(d) to grant holders of conversion or option rights under bonds issued by the Company or its subordinated German or foreign group companies a subscription right to new shares as they would be entitled to after exercising their conversion or option rights or after fulfillment of an agreed conversion obligation;
(e) to implement a so-called scrip dividend, whereby shareholders are offered the option of contributing their dividend entitlement (in whole or in part) to the Company as a contribution in kind in return for the granting of new shares;

(f) if shares are to be issued to a member of the Company’s Management Board or to a person who is in an employment relationship with the Company or one of its affiliated companies; restrictions relating to the shares issued may be agreed, and

(g) to satisfy an option agreed with underwriters in connection with an issue of shares in the Company (or American Depositary Shares representing them) to purchase additional shares or American Depositary Shares (so-called Greenshoe option).

The total number of new shares issued from the Authorized Capital under the authorizations pursuant to sentence 4 letter a) to c) above, excluding subscription rights, may not exceed 20% of the share capital stock, either at the time this authorization takes effect or—if this value is lower—at the time it is exercised. The aforementioned 20% limit shall include (i) those shares which are used to service conversion or option rights or conversion or option obligations or subscription rights of the issuer, (ii) treasury shares which were sold during the term of this authorization until its exercise under exclusion of subscription rights (with the exception of treasury shares sold in accordance with letter b) paragraphs (v), (vi) or (vii) of the resolution on agenda item 8 of the Annual General Meeting on August 19, 2019).

The new shares shall participate in profits from the beginning of the first financial year for which the annual financial statements have not yet been submitted to the Annual General Meeting at the time of registration of the implementation of the capital increase.

The Management Board is authorized to determine further details of the capital increase and its implementation with the approval of the Supervisory Board. The Supervisory Board is authorized to amend the wording of Art. 4 par. 5 of the Articles of Association in accordance with the respective utilization of Authorized Capital 2021 and, if Authorized Capital 2021 is not or not fully utilized by June 21, 2026, to delete Art. 4 para. 5 of the Articles of Association after the expiry of the authorization.

(6) The capital stock is conditionally increased by up to EUR 16,212,917 by issuing up to 16,212,917 new no-par value registered shares with a pro-rata share of the share capital of EUR 1.00 per share (Conditional Capital ESOP 2017/2019). The Conditional Capital ESOP 2017/2019 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 August 18, 2017 under agenda item 5 letter a), also as amended by the resolution of the Annual General Meeting on August 19, 2019 under agenda item 6 letter a) and as amended by the resolution
of the Annual General Meeting on June 26, 2020 under agenda item 5 (collectively the “Authorization 2017/2019”). The shares shall be issued at the Exercise Price determined in accordance with the Authorization 2017/2019 in the version applicable at the time of its utilization. The Conditional Capital increase will only be carried out to the extent that the holders of the stock options issued by the Company on the basis of Authorization 2017/2019 exercise their subscription rights and the Company does not fulfill the stock options by delivering treasury shares or by making a cash payment. Insofar as they are created by the exercise of subscription rights up to the start of the Company’s Annual General Meeting, the new shares shall participate in profits from the start of the preceding financial year, otherwise in each case from the start of the financial year in which they are created by the exercise of stock options.

(7) The share capital is conditionally increased by up to EUR 85,754,868 by issuing up to 85,754,868 new registered no-par value shares, each representing a notional value of EUR 1.00 of the share capital (Conditional Capital WSV 2019). The conditional capital increase shall only be carried out to the extent that the holders or creditors of option rights or conversion rights or those under an obligation to convert under warrant-linked or convertible bonds issued in return for cash contributions and issued or guaranteed by the Company or by a subordinate Company group entity up to, and including, 18 August 2024 based on Management Board authorisation as per the shareholder resolution conferring such authorisation passed at the General Meeting of 19 August 2019 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 the Company exercises a right to choose to grant Company 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 utilised for servicing. The new shares are issued at the warrant exercise price or conversion price to be determined in each case in accordance with the aforementioned resolution granting authorisation. The new shares shall carry an entitlement to dividends from the beginning of the financial year in which they are created; as far as the law permits, the Management Board can confer dividend rights of new shares in derogation of the foregoing and of section 60(2) AktG and also for a financial year that has already ended. The Management Board is authorised, subject to Supervisory Board approval, to determine the further details for implementing the conditional capital increase.

(8) The capital stock is conditionally increased by up to EUR 8,418,091 by issuing up to 8,418,091 new no-par value registered common shares with a notional value of EUR 1.00 per share (Conditional Capital ESOP 2021). The Conditional Capital ESOP 2021 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
The shares shall be issued at the exercise price determined in accordance with the Authorization 2021 in the version applicable at the time of its utilization. The conditional capital increase will only be carried out to the extent that the holders of the stock options issued by the Company on the basis of Authorization 2021 exercise their subscription rights and the Company does not fulfill the stock options by delivering treasury shares or by making a cash payment. The new shares shall participate in profits from the beginning of the preceding financial year, provided they are created by the exercise of subscription rights up to the beginning of the Company’s Annual General Meeting; otherwise, they shall participate in profits from the beginning of the financial year in which they are created by the exercise of stock options.

The Management Board is authorized, subject to the consent of the Supervisory Board, to determine the further details of the issue and the further terms and conditions of the employee stock options; in deviation from this, the Supervisory Board shall also decide in this respect for the Company’s members of the Management Board.

The Supervisory Board is authorized to amend the wording of the Articles of Association in accordance with the scope of the capital increase from Conditional Capital 2021.

To the extent that the above paragraphs provide for authorized or conditional capital, the Supervisory Board is authorized to amend the wording of the Articles of Association after expiry of the period for utilization of the authorized capital and in accordance with the extent of capital increases carried out on the basis thereof.

III. The Executive Bodies of the Company

§ 5 Two-Tier System

(1) The Company has a two-tier management and supervisory system consisting of a management body (Management Board) and a supervisory body (Supervisory Board).

(2) The Company’s executive bodies are the Management Board, the Supervisory Board and the General Meeting.

IV. Management Board

§ 6 Composition

(1) The Management Board shall consist of at least two persons. The members of the Management Board are appointed for a maximum term of five years. Reappointments are permitted.

(2) The number of members of the Management Board is otherwise determined by the Supervisory Board.
§ 7 Management, Representation
(1) The members of the Management Board shall conduct the business of the Company in accordance with the law, the Articles of Association and the rules of procedure issued by the Supervisory Board.
(2) The Company shall be represented by two members of the Management Board or by one member of the Management Board jointly with one holder of a general commercial power of representation (Prokurist). If only one member of the Management Board is appointed, the Company will be represented by this individual alone. The Supervisory Board may grant one, several or all members of the Management Board sole power of representation.
(3) The Supervisory Board may, by resolution, authorize members of the Management Board in general or in individual cases to conclude legal transactions simultaneously for the Company and as representatives of a company affiliated with the Company within the meaning of section 15 AktG as well as in individual cases simultaneously for the Company and as representatives of a third party.
(4) The Supervisory Board may appoint a spokesman or a chairperson of the Management Board.
(5) Furthermore, the Supervisory Board shall issue rules of procedure for the Management Board and shall determine in particular which types of business may only be transacted with its consent.

§ 8 Passing of Resolutions
(1) The Management Board is quorate if all members of the Management Board are invited and at least half of its members participate in the adoption of the resolution, unless otherwise required by mandatory law. Members of the Management Board may cast their vote in writing, by telephone, by telex or by means of electronic media.
(2) The resolutions of the Management Board are passed by a majority of the votes cast, unless otherwise required by mandatory law. Abstentions shall not be taken into account. In the event of a tie the chairperson shall have a casting vote, if such person has been appointed. This does not apply to a spokesman of the Management Board who may have been appointed.

V. Supervisory Board
§ 9 Composition, Term of Office and Remuneration
(1) The Supervisory Board shall comprise of six members.
Unless the General Meeting resolves on a shorter period when electing individual Supervisory Board members to be elected by it or for the full Supervisory Board, the Supervisory Board members shall be elected for a period ending no later than the end of the General Meeting which resolves on the discharge for the fourth financial year after the election. The fiscal year in which the term of office begins is not included in this calculation. Re-election is possible.

The successor to a member who leaves the Supervisory Board before the end of his or her term of office shall only be elected for the remainder of the term of office of the member who has left the Supervisory Board.

When electing Supervisory Board members, the General Meeting may for the same period elect a substitute member for several or all Supervisory Board members or as many substitute members as Supervisory Board members and determine the order in which they shall replace the Supervisory Board members who leave the Supervisory Board during their term of office for the remaining term of office.

Each member of the Supervisory Board may resign from office by submitting a written declaration to the Management Board. A period of one month must be observed.

In addition to reimbursement of their expenses, the members of the Supervisory Board shall receive annual compensation of EUR 70,000, the Chair three times this amount and the Vice Chair one and a half times this amount. The Chair of the Audit Committee shall receive an additional annual compensation of EUR 30,000. The respective Chair of another committee shall receive an additional annual compensation of EUR 15,000. An ordinary committee member receives an additional annual remuneration of EUR 5,000 per committee. Members of the Supervisory Board who are only members of the Supervisory Board for part of the financial year or who chair or vice-chair the Supervisory Board or the Audit Committee or another committee shall receive the respective compensation on a pro-rata basis. The same applies insofar as this regulation or this regulation in a specific version is only in force during part of the financial year. If the reimbursement of expenses or the compensation is subject to value added tax, the value added tax shall be paid in addition. In its own interest, the Company shall maintain appropriate D&O liability insurance for its corporate bodies and management, which shall also include the members of the Supervisory Board and be co-insured at the expense of the Company.

§ 10 Chairperson and deputy

The Supervisory Board shall elect a chairperson and a deputy chairperson from among its members for the duration of its term of office. The oldest member of the Supervisory Board in terms of age is the chairperson. The deputy shall have the rights of the chairperson if the latter is prevented from attending or delegates his or her representation to him or her.
If the chairperson or his/her deputy departs prematurely from their office, then the Supervisory Board shall immediately hold a new election to cover the remaining term of office.

§ 11 Convening and passing resolutions

1. As far as possible, the Supervisory Board shall be convened in each calendar quarter. It must be convened twice every calendar half-year.

2. The meetings of the Supervisory Board shall be convened by the chairperson verbally, by telephone, in writing, by fax or by email, stating the agenda.

3. The Supervisory Board is quorate if at least three members participate in the adoption of the resolution. A member also participates in the adoption of a resolution if he or she abstains from voting.

4. Resolutions require a majority of the votes cast by the members of the Supervisory Board not taking into account any abstentions. In the case of a tie, the votes of the chairperson of the Supervisory Board or, if he does not participate in the passing of the resolution, the vote of the spokesman of the Supervisory Board shall be the casting vote.

5. Resolutions of the Supervisory Board are in principle passed at meetings with personal attendance of the members of the Supervisory Board. Absent members of the Supervisory Board may submit their written vote through another member of the Supervisory Board. Unless the chairperson of the Supervisory Board states otherwise in the invitation due to special circumstances of the individual case, it is permissible for Supervisory Board members to participate and cast their vote in a face-to-face meeting by telephone. The Supervisory Board may also vote without convening a meeting by doing so in writing, by telephone, fax, video conference or email, or in a combined resolution. The chairperson shall decide on the form in which resolutions are to be passed. The Rules of Procedure for the Supervisory Board may stipulate that resolutions are to be postponed in individual cases to be specified in more detail.

6. Minutes shall be taken of the meetings of the Supervisory Board and signed by the chairperson of the meeting. If resolutions are passed outside meetings, the minutes must be signed by the chairperson of the Supervisory Board and forwarded to all members without delay.

7. The chairperson is authorized to on behalf of the Supervisory Board make the declarations required to implement the resolutions and to receive the declarations addressed to the Supervisory Board.

8. The Supervisory Board is empowered to resolve upon changes and amendments to the Articles of Association as long as such changes only affect the wording.
§ 12 Rules of Procedure
The Supervisory Board may issue Rules of Procedure for itself within the framework of the statutory provisions and the provisions of these Articles of Association.

§ 13 Committees
The Supervisory Board may form committees and may refer items for resolution to these committees within the scope of what is permitted by law.

VI. General Meeting

§ 14 Venue and convocation
(1) The General Meeting shall take place within the first six months of the expiry of the fiscal year at the registered office of the Company or in a German city with at least 500,000 inhabitants.
(2) The General Meeting shall be convened by the Management Board or by the Supervisory Board.
(3) Extraordinary General Meetings shall be convened when the best interests of the Company so require.
(4) The General Meeting may also be summed via mail (also via simple letter) or via e-mail. The postal and electronic addresses registered in the share register are authoritative.

§ 15 Chairing the General Meeting, Right to Participate, Participation of Supervisory Board Members
(1) The General Meeting shall be chaired by the chairperson of the Supervisory Board or, in his/her absence, by his/her deputy or, in his/her absence, by another person determined by the Supervisory Board. If no such determination has been made, the chairperson of the meeting shall be elected by the General Meeting.
(2) Shareholders registered in the share register are entitled to participate and exercise their voting rights in the General Meeting if they are registered with the Company in good time. The registration to attend the General Meeting must be in German or English and must be received by the Company at least six days prior to the meeting, unless a shorter period, expressed in days, is provided for in the invitation to the General Meeting, at the address and in the form (written form, text form or another (electronic) form further specified by the Company) as stipulated in such invitation. The day of the General Meeting and the day of receipt shall not be counted.
(3) The chairperson of the meeting shall determine the order of items on the agenda as well as the type and form of voting. The chairperson is authorized to limit the question and speaking rights of the shareholders, as appropriate and to the extent permitted by law. In particular, he/she is authorized, at the beginning or during the course of the General Meeting,
to set a reasonable time limit for the entire General Meeting, for discussion of particular items on the agenda or for any particular speech or question. Furthermore, the chairperson of the General Meeting may prematurely close the list of requests to speak and close the debate, as far as this is necessary for the proper execution of the General Meeting.

(4) The chairperson of the General Meeting may permit the video and audio transmission of the General Meeting in whole or in part, including a transmission via the Internet.

§ 16 Procedure, Minutes

(1) Each share carries one vote.

(2) Voting rights may be exercised by representatives. The power of attorney must be granted in text form by other means. The details shall be determined by the Company. They will be announced with the invitation to the General Meeting.

(3) The Management Board is authorized to provide for shareholders to vote without attendance in the General Meeting in written form or by way of electronic communication (postal vote) as well as participate in the General Meeting and exercise all or some of their rights in whole or in part by means of electronic communication without physical participation and without being represented by a proxy (online participation). The Management Board determines the details of the postal vote as well as the scope and procedure of online participation in the invitation to the General Meeting.

(4) Members of the Supervisory Board can attend the meeting by way of video and audio broadcast if they are resident abroad, if permitted by amendments to the law after the entry into force of this paragraph (4) in the version resolved by the General Meeting on 26 June 2020 either in general or subject to a corresponding permission by the Articles of Association, or if the requirements defined by law for such type of attendance are met.

(5) The Management Board can decide that the General Meeting shall be held without the physical presence of the shareholders or their proxies (virtual general meeting) if so allowed by law and if the statutory requirements are met for holding a General Meeting in the form of a virtual General Meeting.

(6) Minutes shall be kept of the proceedings and shall be signed by the chairperson of the Supervisory Board unless a notarial record is required by law.
§ 17 Resolution

(1) Unless a larger majority is required by law or these Articles of Association, resolutions of the General Meeting shall be adopted by a simple majority of the votes cast. To the extent that statutory provisions also require a majority of the share capital present at the time the resolution is adopted, a simple majority of the share capital present shall suffice, unless a larger majority is required by law. In the event of an undecided vote, an agenda item shall be deemed rejected.

(2) However, unless a larger majority is required by law, resolutions to amend the Articles of Association require a majority of at least two-thirds of the votes cast and of the share capital represented, if at least half of the share capital is not represented.

(3) Should no majority be obtained in the first ballot in elections, the candidates with the two highest numbers of votes reached shall be put on a shortlist. If the election results in a tie between these two candidates, the decision shall be made by lot.

VII. Annual Financial Statements, Appropriation of Profits

§ 18 Annual Financial Statements, Management Report

(1) The Management Board shall prepare the Annual Financial Statements and any Management Report as well as the Consolidated Financial Statements and any Group Management Report for the past financial year within the statutory period.

(2) The Management Board shall submit the Annual Financial Statements and any Management Report as well as the Consolidated Financial Statements and any Group Management Report to the Supervisory Board immediately after they have been prepared, together with its proposal to the General Meeting for the appropriation of net profit.

(3) The Supervisory Board shall examine the Annual Financial Statements, any Management Report of the Management Board, the Consolidated Financial Statements and any Group Management Report and the proposal for the appropriation of net profit, and shall report the results of its examination in writing to the General Meeting. It must forward its report to the Management Board within one month of receipt of the documents. Should the Supervisory Board approve the Annual Financial Statements after examination, they shall be adopted unless the Management Board and Supervisory Board decide to leave the adoption of the Annual Financial Statements to the General Meeting.

§ 19 Retained Earnings

(1) Should the Management Board and the Supervisory Board adopt the Annual Financial Statements, they may transfer amounts of up to half of the net profit for the year to retained earnings. In addition, they are authorized to transfer amounts to retained earnings of up to a further quarter of the net profit for the year, as long as the retained earnings do not exceed half of the share capital or insofar as they would not exceed half of the share capital after the transfer.
(2) When calculating the portion of the net profit to be transferred to retained earnings in accordance with paragraph (1), allocations to the statutory reserve and accumulated losses carried forward shall be taken into account in advance.

(3) The General Meeting shall resolve on the appropriation of profits retained resulting from the adopted Annual Financial Statements. It may allocate further portions of the profits retained to retained earnings, carry these profits forward to a new account – also by way of distribution in kind—or distribute them among the shareholders.

VIII. Legal Disputes

§ 20 Jurisdiction of the US Federal Courts

In the case of litigation on the grounds of or in connection with federal or state capital market laws of the United States of America, only the United States District Court for the Southern District of New York or, in the case of it being replaced by any other first-instance Federal Court of the United States of America having jurisdiction over the borough of Manhattan, such court, shall be the competent court of jurisdiction, in each case insofar as this may be determined by these Articles of Association. This shall not affect any exclusive international jurisdiction under German or European law of the court located at the Company’s registered office.

IX. Expenses

§ 21 Formation expenses

(1) The formation costs of the Company shall be borne by FORATIS AG.

(2) The Company shall bear the expenses of the formation of BioNTech SE by conversion of BioNTech AG into a European company (SE) in the amount of up to EUR 100,000.
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 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. 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 August 18, 2024.

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 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, 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 36 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 (Ertragswertaufrechnung).

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.
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.

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 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.

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 Pflichtenahmung) 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. Removal, including repeated removal, 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.

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.

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.
| 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. |
| Delaware | 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. |
| 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. |
| Delaware | 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. |
| Delaware | 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.
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.

Preemptive Rights

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.

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.

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 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:
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.

- 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;

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, 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) 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 deposited securities are held by The Bank of New York Mellon SA/NV as custodian for the depositary.

Each ADS will also represent any other securities, cash or other property which may be held by the depositary. The deposited securities 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. If you hold 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 holder. 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 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:

<table>
<thead>
<tr>
<th>Item</th>
<th>Fee Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property</td>
<td>$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)</td>
</tr>
<tr>
<td>Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates</td>
<td>$0.05 (or less) per ADS</td>
</tr>
<tr>
<td>Any cash distribution to ADS holders</td>
<td>$0.05 (or less) per ADS per calendar year</td>
</tr>
<tr>
<td>Distribution of securities distributed to or from the name of the depositary or its agent when you deposit or withdraw shares</td>
<td></td>
</tr>
<tr>
<td>Depositary services</td>
<td></td>
</tr>
<tr>
<td>Cable and facsimile transmissions (when expressly provided in the deposit agreement)</td>
<td></td>
</tr>
<tr>
<td>Converting foreign currency to U.S. dollars</td>
<td></td>
</tr>
<tr>
<td>Any cash distribution to ADS holders</td>
<td></td>
</tr>
<tr>
<td>As necessary</td>
<td></td>
</tr>
<tr>
<td>As necessary</td>
<td></td>
</tr>
</tbody>
</table>

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 so 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 subdivision, 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 or 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 ADRs 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 ADRs, 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 ADRs from an exchange in the United States on which they were listed and do not list the ADRs on another exchange in the United States or make arrangements for trading of ADRs 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 ADRs 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 ADRs 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 ADRs. 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 ADRs 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 ADRs or distribute any dividends or other distributions on deposited securities to the ADR holders (until they surrender their ADRs) 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.
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 depositary 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 depositary 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 depositary 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 depositary 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 depositary’s reliance on and compliance with instructions received by the depositary through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depositary.

Shareholder Communications; Inspection of Register of Holders of ADSs

The depositary 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 depositary 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 depositary 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 depositary 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 depositary’s compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.
LEASE AGREEMENT

THIS LEASE AGREEMENT ("this Lease") is made as of this 1 day of December, 2017, between TECH PARK 270 III, LLC, a Maryland limited liability company ("Landlord"), and KITE PHARMA, INC., a Delaware corporation ("Tenant").

BASIC LEASE PROVISIONS

Address: Suite 200, 930 Clopper Road, Gaithersburg, Maryland 20878-1301.

Premises: That portion of the Project, containing approximately 26,103 rentable square feet, as shown as the hatched area on Exhibit A. Gaudreau, Inc., Landlord’s architect, has measured the area of the Premises pursuant to the 1996 Standard Method of Measuring Floor Area in Office Buildings as adopted by the Building Owners and Managers Association (ANSI/BOMA Z65.1-1996) ("BOMA Standards"). Tenant acknowledges receipt of such measurement and confirms that (a) Tenant has had an opportunity to confirm such measurement with an architect of its selection before the Commencement Date, and (b) such measurement shall be conclusive as to the area of the Premises.

Project: The real property on which the building ("Building") in which the Premises are located, together with all improvements thereon and appurtenances thereto as described on Exhibit B.

Base Rent: [***] per month Rentable Area of Premises: [***] sq. ft.

Rent Adjustment Percentage: [***]%

Deposit: None Tenant’s Share of Operating Expenses: [***]%

Target Commencement Date: December 1, 2017

Permitted Use: Biopharmaceutical research and manufacturing, research and development laboratory, related office and other related uses consistent with the character of the Project and otherwise in compliance with the provisions of Section 7 hereof.

Address for Rent Payment: For check payments remit to:

Landlord’s Notice Address:

Copyright © 2007, Alexandria Real Estate Equities, Inc.
ALL RIGHTS RESERVED. Confidential and Proprietary - Do Not Copy or Distribute. Alexandria and the Alexandria Logo are registered trademarks of Alexandria Real Estate Equities, Inc.
For overnight courier remit to:

[***]
[***]
[***]

Tenant's Notice Address:

[***]
[***]
[***]

With a copy to:

[***]
[***]
[***]

The following Exhibits and Addenda are attached hereto and incorporated herein by this reference:

☒ EXHIBIT A - PREMISES DESCRIPTION
☒ EXHIBIT B - DESCRIPTION OF PROJECT
☒ EXHIBIT C-1 - LANDLORD'S WORK
☒ EXHIBIT C-2 - WORK LETTER
☒ EXHIBIT D - COMMENCEMENT DATE
☒ EXHIBIT E - RULES AND REGULATIONS
☒ EXHIBIT F - TENANT’S PERSONAL PROPERTY

1. Lease of Premises. Upon and subject to all of the terms and conditions hereof, Landlord hereby leases the Premises to Tenant and Tenant hereby leases the Premises from Landlord. The portions of the Project that are for the non-exclusive use of tenants of the Project are collectively referred to herein as the "Common Areas." Landlord reserves the right to modify Common Areas, provided that such modifications do not materially adversely affect Tenant’s use of the Premises for the Permitted Use or Tenant’s rights hereunder. Subject to a Taking (as defined in Section 19) and Force Majeure (as defined in Section 34), Tenant shall have access to the Premises (and the right to use the Common Areas and parking facilities subject to a Taking, Force Majeure, and the provisions of Section 13) 24 hours per day, 7 days per week, 365/366 days per year during the Term. Tenant shall have the exclusive right to use the loading dock serving the Premises.

2. Delivery; Acceptance of Premises; Commencement Date. Landlord shall use reasonable efforts to deliver the Premises to Tenant on or before the Target Commencement Date so as to make the Premises available to Tenant for Tenant’s Work under the Work Letter (as long as Tenant delivers evidence of the insurance required hereby and by the Work Letter) and to allow Landlord to perform Landlord’s Work ("Delivery" or "Deliver"). If Landlord fails to timely Deliver the Premises, Landlord shall not be liable to Tenant for any loss or damage resulting therefrom, and this Lease shall not be void or voidable except as provided herein. If Landlord does not Deliver the Premises within 60 days of the Target Commencement Date for any reason other than Force Majeure Delays and Tenant Delays, this Lease may be terminated by Tenant by written notice to Landlord, and if so terminated by either: (a) the Security Deposit, or any balance thereof (i.e., after deducting therefrom all amounts to which Landlord is entitled under the provisions of this Lease), shall be returned to Tenant, and (b) neither Landlord nor Tenant shall have any further rights, duties or obligations under this Lease, except with respect to provisions that expressly survive termination of this Lease. As used herein, (a) “Landlord’s Work”
means the work of constructing the improvements to the Premises described on Exhibit C-1, (b) “Force Majeure Delays” means delays arising by reason of any Force Majeure, and (c) “Substantially Completed” or variations thereof shall have the meaning set forth in the Work Letter attached hereto as Exhibit C-2. If Tenant does not elect to void this Lease within 5 business days of the lapse of such 60 day period, such right to void this Lease shall be waived and this Lease shall remain in full force and effect.

The “Commencement Date” shall mean the date of this Lease. The “Rent Commencement Date” shall be the date that is 10 months after the date on which Landlord delivers the Premises to Tenant, subject to extension to the extent that Tenant is actually delayed in the design or construction of the Tenant Improvements (as defined in Exhibit C-2) by Landlord or by Force Majeure Delays. Upon request of Landlord, Tenant shall execute and deliver a written acknowledgment of the Commencement Date, the Rent Commencement Date, and the expiration date of the Term when such are established in the form of the “Acknowledgement of Commencement Date” attached to this Lease as Exhibit D; provided, however, Tenant’s failure to execute and deliver such acknowledgment shall not affect Landlord’s rights hereunder. The “Term” of this Lease shall be the Base Term, as defined above in the Basic Lease Provisions and the Extension Term that Tenant may elect pursuant to Section 40 hereof.

Except as set forth in the Work Letter, if applicable, and in this Section 2: (i) Tenant shall accept the Premises in their condition as of the Commencement Date, subject to all applicable Legal Requirements (as defined in Section 7 hereof); (ii) Landlord shall have no obligation for any defects in the Premises; and (iii) Tenant’s taking possession of the Premises shall be conclusive evidence that Tenant accepts the Premises and that the Premises were in good condition at the time possession was taken. Any occupancy of the Premises by Tenant before the Commencement Date shall be subject to all of the terms and conditions of this Lease (other than the obligation to pay Rent).

Tenant agrees and acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of all or any portion of the Premises or the Project, and/or the suitability of the Premises or the Project for the conduct of Tenant’s business, and Tenant waives any implied warranty that the Premises or the Project are suitable for the Permitted Use. This Lease constitutes the complete agreement of Landlord and Tenant with respect to the subject matter hereof and supersedes any and all prior representations, inducements, promises, agreements, understandings and negotiations that are not contained herein. Landlord in executing this Lease does so in reliance upon Tenant’s representations, warranties, acknowledgments and agreements contained herein.

Notwithstanding the foregoing provisions of this Section 2, Tenant shall have a period of 60 days after the Substantial Completion of Landlord’s Work to reasonably identify in writing any latent defects in the mechanical, electrical, and plumbing systems and the structural components serving the Premises. For purposes of this paragraph, “latent defects” means those material defects in such systems or components that could not have been identified or discovered through a reasonable inspection of such systems or components conducted by a qualified technician. Landlord will promptly repair such identified latent defects at Landlord’s cost (and not as part of “Operating Expenses (as defined below)), subject to Landlord’s confirmation that such defects are, in fact, latent defects.
3. Rent.

(a) Base Rent. The first month’s Base Rent shall be due and payable on delivery of an executed copy of this Lease to Landlord. Beginning on the Rent Commencement Date, Tenant shall pay to Landlord in advance, without demand, abatement, deduction or set-off, monthly installments of Base Rent on or before the first day of each calendar month during the Term hereof, in lawful money of the United States of America, at the office of Landlord for payment of Rent set forth above, or to such other person or at such other place as Landlord may from time to time designate in writing. Payments of Base Rent for any fractional calendar month shall be prorated. The obligation of Tenant to pay Base Rent and other sums to Landlord and the obligations of Landlord under this Lease are independent obligations. Tenant shall have no right at any time to abate, reduce, or set-off any Rent (as defined in Section 5) due hereunder except for any abatement as may be expressly provided in this Lease.

(b) Additional Rent. In addition to Base Rent, Tenant agrees to pay to Landlord as additional rent ("Additional Rent"): (i) Tenant’s Share of "Operating Expenses" (as defined in Section 5), and (ii) any and all other amounts Tenant assumes or agrees to pay under the provisions of this Lease, including, without limitation, any and all other sums that may become due by reason of any default of Tenant or failure to comply with the agreements, terms, covenants and conditions of this Lease to be performed by Tenant, after any applicable notice and cure period.

4. Base Rent Adjustments. Base Rent shall be increased on each anniversary of the Rent Commencement Date (each an "Adjustment Date") by multiplying the Base Rent payable immediately before such Adjustment Date by the Rent Adjustment Percentage and adding the resulting amount to the Base Rent payable immediately before such Adjustment Date. Base Rent, as so adjusted, shall thereafter be due as provided herein. Base Rent adjustments for any fractional calendar month shall be prorated.

5. Operating Expense Payments. Landlord shall deliver to Tenant a written estimate of Operating Expenses for each calendar year during the Term ("Annual Estimate"), which may be revised by Landlord from time to time during such calendar year. Beginning on the Rent Commencement Date, Tenant shall pay Landlord on or before the first day of each calendar month during the Term hereof an amount equal to 1/12th of Tenant’s Share of the Annual Estimate. Payments for any fractional calendar month shall be prorated. With the exception of utilities consumed within the Premises, Tenant shall not be obligated to pay Tenant’s Share of Operating Expenses before the Rent Commencement Date.

The term “Operating Expenses” means all costs and expenses of any kind or description whatsoever incurred or accrued each calendar year by Landlord with respect to the Project (including, without duplication, Taxes (as defined in Section 9), capital repairs and improvements amortized on a straight-line basis over the useful life of such capital items, and the costs of Landlord’s third party property manager in the amount of [***]% of Base Rent or, if there is no third party property manager, administration rent in the amount of [***]% of Base Rent), excluding only:

Copyright © 2007, Alexandria Real Estate Equities, Inc.
ALL RIGHTS RESERVED. Confidential and Proprietary - Do Not Copy or Distribute. Alexandria and the Alexandria Logo are registered trademarks of Alexandria Real Estate Equities, Inc.
(a) the original construction costs of the Project and renovation prior to the date of this Lease and costs of correcting defects in such original construction or renovation or latent defects;

(b) capital expenditures for expansion of the Project or any other capital improvements, equipment, replacements, or repairs incurred in connection with the Project except for any capital improvements, equipment, replacements, or repairs that are reasonably intended to reduce Operating Expenses, but only to the extent of reasonably intended cost savings, or (ii) that are required under any Legal Requirement enacted after the date of Delivery, and in each case amortized as set forth in the second paragraph of this Section 5;

(c) interest, principal payments of Mortgage (as defined in Section 27) debts of Landlord, financing costs and amortization of funds borrowed by Landlord, whether secured or unsecured and all payments of base rent (but not taxes or operating expenses) under any ground lease or other underlying lease of all or any portion of the Project;

(d) depreciation of the Project (except for capital improvements, the cost of which are includable in Operating Expenses);

(e) advertising, legal and space planning expenses and leasing commissions and other costs and expenses incurred in procuring and leasing space to tenants for the Project, including any leasing office maintained in the Project, free rent and construction allowances for tenants;

(f) legal and other expenses incurred in the negotiation or enforcement of leases;

(g) completing, fixtures, improving, renovating, painting, redecorating or other work, which Landlord pays for or performs for other tenants within their premises, and costs of correcting defects in such work;

(h) costs of utilities outside normal business hours sold to tenants of the Project;

(i) costs to be reimbursed by other tenants of the Project or Taxes to be paid directly by Tenant or other tenants of the Project, whether or not actually paid;

(j) the wages and benefits of any employees who do not devote substantially all of their employed time to the Project unless such wages and benefits are prorated to reflect time spent on operating and managing the Project vis-à-vis time spent on matters unrelated to operating and managing the Project; provided, however, that in no event shall Operating Expenses include wages and/or benefits attributable to personnel above the level of property manager;

(k) general organizational, administrative and overhead costs relating to maintaining Landlord’s existence, either as a corporation, partnership, or other entity, including general corporate, legal and accounting expenses;

(l) costs (including attorneys’ fees and costs of settlement, judgments and payments in lieu thereof) incurred in connection with disputes with tenants, other occupants, or prospective tenants, and costs and expenses, including legal fees, incurred in connection with negotiations or disputes with employees, consultants, management agents, leasing agents, purchasers or mortgagees of the Building;

(m) costs incurred by Landlord due to the violation by Landlord, its employees, agents or contractors or any tenant of the terms and conditions of any lease or lease of space in the Project or any Legal Requirement (as defined in Section 29).
(n) penalties, fines or interest incurred as a result of Landlord’s inability or failure to make payment of Taxes and/or to file any tax or informational returns when due, or from Landlord’s failure to make any payment of Taxes required to be made by Landlord hereunder before delinquency;

(o) overhead and profit increment paid to Landlord or to subsidiaries or affiliates of Landlord for goods and/or services in or to the Project to the extent the same exceeds the costs of such goods and/or services rendered by unaffiliated third parties on a competitive basis;

(p) costs of Landlord’s charitable or political contributions, or of fine art maintained at the Project;

(q) costs in connection with services (including electricity), items or other benefits of a type that are not standard for the Project and that are not available to Tenant without specific charges therefor, but which are provided to another tenant or occupant of the Project, whether or not such other tenant or occupant is specifically charged therefor by Landlord;

(r) costs incurred in the sale or refinancing of the Project;

(s) net income taxes of Landlord or the owner of any interest in the Project (except to the extent such net income taxes are in substitution for any Taxes payable hereunder), franchise, capital stock, gift, estate or inheritance taxes or any federal, state or local documentary taxes imposed against the Project or any portion thereof or interest therein;

(t) reserves for future repairs and replacements;

(u) any expenses otherwise includable within Operating Expenses to the extent actually reimbursed by persons other than tenants of the Project under leases for space in the Project;

(v) any liabilities, costs, or expenses associated with or incurred in connection with the remediation of environmental conditions or otherwise arising from the presence of any Hazardous Materials (as defined below) in, on, or about the Project (i) that existed before the Commencement Date, (ii) caused solely by Landlord, or (iii) caused by another tenant of the Project or a third party unrelated to Tenant and any Tenant Party (collectively, “Excluded Hazardous Materials Events”)

In no event shall Landlord collect Operating Expenses from Tenant and all other tenants of the Building in an amount in excess of what Landlord actually incurred for the items included Operating Expenses (without mark-up).

In addition, notwithstanding anything to the contrary contained in this Lease, Operating Expenses incurred or accrued by Landlord with respect to any capital improvements that are reasonably expected by Landlord to reduce overall Operating Expenses (for example, without limitation, by reducing energy usage at the Project) (“Energy Savings Costs”) shall be amortized over a period of years equal to the least of (A) 7 years, (B) the useful life of such capital items, and (C) the quotient of (i) the Energy Savings Costs, divided by (ii) the annual amount of Operating Expenses reasonably expected by Landlord to be saved as a result of such capital improvements.

Notwithstanding any contrary provision contained in this Lease, the Controllable Operating Expenses (as defined below) shall be capped so that no increase in the Controllable Operating Expenses exceeds [***]% per calendar year based on the actual Controllable Operating Expenses incurred during calendar year 2017. As a result, the actual annual increase in Controllable Operating Expenses in any given calendar year from and after calendar year 2017 may be less than or equal to [***]% (but shall not
exceed [***%]). The calculations made under this paragraph shall be made on a current basis with reference to the calendar year in question, and no retrospective adjustments shall be made at the end of the Term for the preceding calendar years. For purposes of this Lease, (1) “Controllable Operating Expenses” mean all Operating Expenses except Non-Controllable Operating Expenses, and (2) “Non-Controllable Operating Expenses” means insurance premiums, real estate taxes, costs of snow and ice removal, utilities costs, and costs of repairs and replacements to Building Systems (as defined below) as long as such repairs and replacements are consistent in quality and kind with the Building Systems being repaired or replaced.

Within 90 days after the end of each calendar year (or such longer period as may be reasonably required), Landlord shall furnish to Tenant a statement (an “Annual Statement”) showing in reasonable detail: (a) the total and Tenant’s Share of actual Operating Expenses for the previous calendar year, and (b) the total of Tenant’s payments in respect of Operating Expenses for such year. If Tenant’s Share of actual Operating Expenses for such year exceeds Tenant’s payments of Operating Expenses for such year, the excess shall be due and payable by Tenant as Rent within 30 days after delivery of such Annual Statement to Tenant. If Tenant’s payments of Operating Expenses for such year exceed Tenant’s Share of actual Operating Expenses for such year Landlord shall pay the excess to Tenant within 30 days after delivery of such Annual Statement, except that after the expiration, or earlier termination of the Term or if Tenant is delinquent in its obligation to pay Rent, Landlord shall pay the excess to Tenant after deducting all other amounts due Landlord.

Within 90 days after the receipt of an Annual Statement by Tenant (“Review Period”), if Tenant disputes the amount set forth in the Annual Statement, Tenant’s employees or an independent certified public accountant designated by Tenant, may, after reasonable notice to Landlord and at reasonable times, inspect Landlord’s records at Landlord’s offices. If Tenant does not so dispute the Annual Statement by the expiration of the Review Period, the Annual Statement shall be final and binding on Tenant. If after such inspection Tenant notifies Landlord in writing that Tenant still disputes such amounts, a certification as to the proper amount shall be made by an independent certified public accountant selected by Landlord and reasonably approved by Tenant and Landlord. Landlord shall cooperate in good faith with Tenant and the accountant to show Tenant and the accountant the information upon which the certification is to be based. However, if such certification by the accountant proves that the Operating Expenses set forth in the Annual Statement were overstated by more than 3%, then the reasonable cost of Tenant’s initial review, the accountant, and the cost of such certification shall be paid for by Landlord. Promptly following the parties’ receipt of such certification, the parties shall make such appropriate payments or reimbursements, as the case may be, to each other, as are determined to be owing pursuant to such certification.

“Tenant’s Share” shall be the percentage set forth in the Basic Lease Provisions as Tenant’s Share as reasonably adjusted by Landlord for changes in the physical size of the Premises or the Project occurring thereafter. Landlord may equitably adjust Tenant’s Share for any item of expense or cost reimbursable by Tenant that relates to a repair, replacement, or service that benefits only the Premises or only a portion of the Project that includes the Premises or that varies with occupancy or use. Base Rent, Tenant’s Share of Operating Expenses and all other amounts payable by Tenant to Landlord hereunder are collectively referred to herein as “Rent.”
6. Reserved.

7. Use. The Premises shall be used solely for the Permitted Use set forth in the Basic Lease Provisions, and in compliance with all laws, orders, judgments, ordinances, regulations, codes, directives, permits, licenses, covenants and restrictions now or hereafter applicable to the Premises, and to the use and occupancy thereof, including, without limitation, the Americans With Disabilities Act, 42 U.S.C. § 12101, et seq. (together with the regulations promulgated pursuant thereto, “ADA”) (collectively, “Legal Requirements” and each, a “Legal Requirement”). Tenant shall, upon 5 days’ written notice from Landlord, discontinue any use of the Premises that is declared by any Governmental Authority (as defined in Section 9) having jurisdiction to be a violation of a Legal Requirement. Tenant will not use or permit the Premises to be used for any purpose or in any manner that would void Tenant’s or Landlord’s insurance, increase the insurance risk, or cause the disallowance of any sprinkler or other credits. Tenant shall not permit any part of the Premises to be used as a “place of public accommodation”, as defined in the ADA or any similar legal requirement. Tenant shall reimburse Landlord promptly upon demand for any additional premium charged for any such insurance policy by reason of Tenant’s failure to comply with the provisions of this Section or otherwise caused by Tenant’s use and/or occupancy of the Premises. Tenant will use the Premises in a careful, safe and proper manner and will not commit or permit waste, overload the floor or structure of the Premises, subject the Premises to use that would damage the Premises or obstruct or interfere with the rights of Landlord or other tenants or occupants of the Project, including conducting or giving notice of any auction, liquidation, or going out of business sale on the Premises, or using or allowing the Premises to be used for any unlawful purpose. Tenant shall cause any equipment or machinery to be installed in the Premises so as to reasonably prevent sounds or vibrations from the Premises from extending into Common Areas, or other space in the Project. Tenant shall not place any machinery or equipment weighing 500 pounds or more in or upon the Premises or transport or move such items through the Common Areas of the Project without the prior written consent of Landlord. Except as may be provided under the Work Letter, Tenant shall not, without the prior written consent of Landlord, use the Premises in any manner that will require ventilation, air exchange, heating, gas, steam, electricity or water beyond the existing capacity of the Project as proportionately allocated to the Premises based upon Tenant’s Share as usually furnished for the Permitted Use.

(a) Modifications to Common Areas. Landlord shall be responsible for the compliance of the Common Areas of the Project with the ADA and other Legal Requirements as of the Commencement Date (and shall not include such costs in Operating Expenses). From and after the Commencement Date, Landlord shall, as an Operating Expense (to the extent such Legal Requirement is generally applicable to similar buildings in the area in which the Project is located) or at Tenant’s expense (to the extent such Legal Requirement is applicable solely by reason of Tenant’s, as compared to other tenants of the Project, particular use of the Premises) make any alterations or modifications to the Common Areas or the exterior of the Building that are required by Legal Requirements, including the ADA. Tenant, at its sole expense, shall make any alterations or modifications to the interior of the Premises that are required by Legal Requirements (including, without limitation, compliance of the Premises with the ADA). Notwithstanding any other provision herein to the contrary, Tenant shall be responsible for any and all demands, claims, liabilities, losses, costs, expenses, actions, causes of action, damages or judgments, and all reasonable expenses incurred in investigating or resisting the same (including, without limitation, reasonable attorneys’ fees, charges and disbursements and costs of suit) (collectively, “Claims”) arising out of or in connection with the failure of the Premises to comply with any Legal Requirement, and Tenant shall indemnify, defend, hold and save Landlord harmless from and against any and all Claims arising out of or in connection with any failure of the Premises to comply with any Legal Requirement.

(b) Alexandria Fitlab. As long as Tenant is not in Default, Tenant’s on-site employees shall have a non-exclusive license to use on a complimentary basis the Alexandria Fitlab located at 910 Clopper Road, Gaithersburg, Maryland that is owned by an affiliate of Landlord (“910 Clopper Landlord”). Although the Alexandria Fitlab does not form a part of the Premises, the provisions of this Lease (i) governing Tenant’s use, operation, and enjoyment of the Premises as applicable to Tenant’s...
use of the Alexandria FitLab, (ii) imposing obligations on Tenant for matters occurring in, on, within, or about the Premises or arising out of the use or occupancy of the Premises (including, but not limited to, those obligations relating to insurance and indemnification) as applicable to Tenant’s use of the Alexandria FitLab, or (iii) limiting Landlord’s liability, shall apply with equal force to Tenant’s use of the Alexandria FitLab. Landlord shall have the right at any time and from time to time in the exercise of its sole and absolute subjective discretion to eliminate, reconfigure, relocate, or modify the Alexandria FitLab or modify its hours of availability for Tenant’s use, it being understood and agreed that Landlord makes no guaranty, assurance, or representation to Tenant that the Alexandria FitLab will remain available for use by Tenant during all or any part of the Term. Landlord or its designee may specifically condition the use of the Alexandria FitLab by any employee of Tenant upon such employee’s execution and delivery of the standard license, indemnification, and waiver agreement required by Landlord or, if applicable, any operator of the Alexandria FitLab. Tenant and its employees shall be required to comply with all of the rules, regulations, conditions, and scheduling procedures of the 910 Clopper Landlord in connection with the use of the Alexandria FitLab. As of the Commencement Date, Tenant shall cause the 910 Clopper Landlord to be named as an additional insured under the commercial general liability policy of insurance that Tenant is required to maintain under this Lease. If Tenant Defaults in its obligations under this Section 7(b), Landlord shall have the right, in addition to any other rights and remedies available to Landlord for a Default by Tenant, to terminate immediately Tenant’s license to use the Alexandria FitLab. The expiration or earlier termination of this Lease shall automatically terminate the license hereby granted to Tenant to so use the Alexandria FitLab.

(c) Food Vending Machines; Micro-Market Systems. Tenant shall have the right to install within the Premises, without Landlord’s consent but otherwise subject to the provisions of Section 12, one or more food vending machines and micro-market systems for the use by Tenant’s employees (collectively, “Food Service Equipment”). Tenant shall install, use, operate, maintain, and replace the Food Service Equipment in accordance with applicable Legal Requirements (including, but not limited to, obtaining and maintaining at Tenant’s sole cost and expense any permits or licenses to install, use, and operate the Food Service Equipment). In no event shall the Food Service Equipment dispense or offer any alcoholic beverages, tobacco products, or chewing gum. Landlord shall have no obligation, responsibility, or liability for the operation of the Food Service Equipment. All food sold or dispensed from the Food Service Equipment shall be free from spoilage and decay and shall not be suspect of contamination from organisms causing foodborne illness.

8. Holding Over. If Tenant remains in possession of the Premises after the expiration or earlier termination of the Term, (a) Tenant shall become a tenant at sufferance upon the terms of this Lease except that (i) the monthly rental for the first 60 days of the holdover shall be equal to [***]% of Base Rent (and [***]% of the Additional Rent) in effect during the last 30 days of the Term, and (ii) from and after the initial 60 days of the holdover, the monthly rental shall be equal to [***]% of Base Rent (and [***]% of the Additional Rent) in effect during the last 30 days of the Term, and (b) Tenant shall be responsible for all damages suffered by Landlord resulting from or occasioned by Tenant’s holding over, including consequential damages. No holding over by Tenant, whether with or without consent of Landlord, shall operate to extend this Lease except as otherwise expressly provided, and this Section 8 shall not be construed as consent for Tenant to retain possession of the Premises. Acceptance by Landlord of Rent after the expiration of the Term or earlier termination of this Lease shall not result in a renewal or reinstatement of this Lease.

9. Taxes. Landlord shall pay, as part of Operating Expenses, all taxes, levies, fees, assessments and governmental charges of any kind, existing as of the Commencement Date or thereafter enacted (collectively referred to as “Taxes”), imposed by any federal, state, regional, municipal, local or other governmental authority or agency, including, without limitation, quasi-public agencies (collectively, “Governmental Authority”) during the Term with respect to the land, buildings, and other improvements comprising the Project, including, without limitation, all Taxes: (i) imposed on or measured by or based, in whole or in part, on real property or (on gross receipts received by) Landlord under this Lease.
10. Parking. Subject to all Legal Requirements, Force Majeure, a Taking (as defined in Section 19 below) and the exercise by Landlord of its rights hereunder, Tenant shall have the right, in common with other tenants of the Project pro rata in accordance with the rentable area of the Premises and the rentable areas of the Project occupied by such other tenants, to park in those areas designated for non-reserved parking, subject in each case to Landlord’s reasonable rules and regulations at no cost to Tenant. Landlord may allocate parking spaces among Tenant and other tenants in the Project pro rata as described above if Landlord determines that such parking facilities are becoming crowded. Landlord shall not be responsible for enforcing Tenant’s parking rights against any third parties, including other tenants of the Project. As of the Commencement Date, the current parking ratio is 3.3 standard sized spaces per 1,000 leased rentable square feet.


(a) General. Landlord shall provide, subject to the terms of this Section 11, janitorial services to the Common Areas, water, electricity, heat, light, power, telephone, sewer, and other utilities (including gas and fire sprinklers) to the extent the Project is plumbed for such services), and refuse and trash collection (collectively, “Utilities”). Landlord shall pay, as Operating Expenses or subject to Tenant’s reimbursement obligation, for all Utilities used on the Premises, all maintenance charges for Utilities, and any storm sewer charges or other similar charges for Utilities imposed by any Governmental Authority or Utility provider, and any taxes, penalties, surcharges or similar charges thereon. Landlord may cause, at Tenant’s expense, any Utilities to be separately metered or charged directly to Tenant by the provider. Landlord shall, at its cost, install separate electrical submeters in the Premises. Tenant shall pay directly to the Utility provider or reimburse Landlord (as Additional Rent), prior to delinquency, any separately metered Utilities and services that may be furnished to Tenant or the Premises during the Term. Tenant shall pay, as part of Operating Expenses, its share of all charges for jointly metered Utilities based upon consumption, as reasonably determined by Landlord based upon the actual utility rates without markup. Except as provided in paragraph (b) below, no interruption or failure of Utilities from any cause whatsoever shall result in eviction or constructive eviction of Tenant, termination of this Lease or the abatement of Rent. Tenant agrees to limit use of water and sewer with respect to Common Areas to normal restroom use. Landlord shall use commercially reasonable efforts to promptly restore the utilities to the extent the cause of the interruption or the means to restore the same is within Landlord’s reasonable control.
(b) Abatement. Notwithstanding the provisions of paragraph (a) above, if Tenant is prevented from using, and does not use, the Premises or any material portion thereof as a result of any failure of Landlord to provide or repair/recover Utilities in accordance with this Section 11, then Tenant shall give Landlord written notice of such failure. If such failure continues for 3 consecutive days after Landlord’s receipt of any such notice (“Eligibility Period”) and is solely due to Landlord’s gross negligence or willful misconduct (to the extent within Landlord’s reasonable control) (“Abatement Event”), then Base Rent and Operating Expenses shall be abated or reduced, as the case may be, after the expiration of the Eligibility Period, for such time that such Abatement Event continues (“Abatement Period”), in the proportion that the rentable area of the portion of the Premises that Tenant is actually prevented from using, and does not use, bears to the total rentable area of the Premises. Tenant’s right to abate Base Rent under this Section 11 shall be Tenant’s sole and exclusive remedy at law or in equity for an Abatement Event. This Section shall not apply to any event described in Section 18 or 19.

(c) Energy Usage Data. Tenant agrees to provide Landlord with access to Tenant’s water and/or energy usage data on a monthly basis, either by providing Tenant’s applicable utility login credentials to Landlord’s designated online portal, or by another delivery method reasonably agreed to by Landlord and Tenant. The costs and expenses incurred by Landlord in connection with receiving and analyzing such water and/or energy usage data (including, without limitation, as may be required pursuant to applicable Legal Requirements) shall be included as part of Operating Expenses.

12. Alterations and Tenant’s Property. Any alterations, additions, or improvements made to the Premises by or on behalf of Tenant, including additional locks or bolts of any kind or nature upon any doors or windows in the Premises, but excluding installation, removal or realignment of furniture systems (other than removal of furniture systems owned or paid for by Landlord) not involving any modifications to the structure or connections (other than by ordinary plugs or jacks) to Building Systems (as defined in Section 13) (“Alterations”) shall be subject to Landlord’s prior written consent, which may be given or withheld in Landlord’s sole discretion if any such Alteration affects the structure or Building Systems, but which shall otherwise be unreasonably withheld or delayed. Tenant may construct nonstructural Alterations in the Premises without Landlord’s prior approval if the aggregate cost of all such work in any 12 month period does not exceed $[***] (“Notice-Only Alteration”), provided Tenant notifies Landlord in writing of such intended Notice-Only Alteration, and such notice shall be accompanied by plans, specifications, work contracts and such other information concerning the nature and cost of the Notice-Only Alteration as may be reasonably requested by Landlord, which notice and accompanying materials shall be delivered to Landlord not less than 15 days in advance of any proposed construction. If Landlord approves any Alterations, Landlord may impose such conditions on Tenant in connection with the commencement, performance and completion of such Alterations as Landlord may deem appropriate in Landlord’s reasonable discretion. Any request for approval shall be in writing, delivered not less than 15 business days in advance of any proposed construction, and accompanied by plans, specifications, bid proposals, work contracts and such other information concerning the nature and cost of the alterations as may be reasonably requested by Landlord, including the identities and mailing addresses of all persons performing work or supplying materials. Landlord’s right to review plans and specifications and to monitor construction shall be solely for its own benefit, and Landlord shall have no duty to ensure that such plans and specifications or construction comply with applicable Legal Requirements. Tenant shall cause, at its sole cost and expense, all Alterations to comply with insurance requirements and with Legal Requirements and shall implement any alteration or modification required by Legal Requirements as a result of any Alterations. Tenant shall reimburse Landlord for, and indemnify and hold Landlord harmless from, any expense incurred by Landlord by reason of faulty work done by Tenant or its contractors, delays caused by such work, or inadequate cleanup.

Copyright © 2007, Alexandria Real Estate Equities, Inc.  
ALL RIGHTS RESERVED. Confidential and Proprietary - Do Not Copy or Distribute. Alexandria and the Alexandria Logo are registered trademarks of Alexandria Real Estate Equities, Inc.
(a) Insurance. Tenant shall provide (and cause each contractor or subcontractor to provide) certificates of insurance (in form and substance satisfactory to Landlord; form ACORD 28 [2006/07] is not satisfactory to Landlord) for workers’ compensation and other coverage in amounts and from an insurance company satisfactory to Landlord protecting Landlord against liability for personal injury or property damage during construction. Upon completion of any Alterations, Tenant shall deliver to Landlord: (i) sworn statements setting forth the names of all contractors and subcontractors who did the work and final lien waivers from all such contractors and subcontractors; and (ii) “as built” plans for any such Alteration (if applicable).

(b) Tenant’s Property; Installations. Other than (i) the items, if any, listed on Exhibit F attached hereto, (ii) any items agreed by Landlord in writing to be included on Exhibit F in the future, and (iii) any trade fixtures, machinery, equipment and other personal property not paid for out of the TI Allowance (as defined in the Work Letter) that may be removed without material damage to the Premises, which damage shall be repaired (including capping or terminating utility hook-ups behind walls) by Tenant during the Term (collectively, “Tenant’s Property”), all property of any kind paid for with the TI Allowance, all Alterations, real property fixtures, built-in machinery and equipment, built-in casework and cabinets and other similar additions and improvements built into the Premises so as to become an integral part of the Premises, such as flame hoods that penetrate the roof or plenum area, built-in cold rooms, built-in warm rooms, walk-in cold rooms, walk-in warm rooms, deionized water systems, glass washing equipment, autoclaves, chillers, built-in plumbing, electrical and mechanical equipment and systems, and any power generator and transfer switch (collectively, “Installations”) shall be and shall remain the property of Landlord during the Term and following the expiration or earlier termination of the Term, shall not be removed by Tenant at any time during the Term and shall remain upon and be surrendered with the Premises as a part thereof in accordance with Section 28 following the expiration or earlier termination of this Lease; provided, however, that (A) Landlord shall, at the time its approval of such Installation is requested or at the time it receives notice of a Notice-Only Alteration, notify Tenant if it has elected to cause Tenant to remove such Installation upon the expiration or earlier termination of this Lease, and (B) in no event shall Tenant have any obligation to remove from the Premises at the expiration or earlier termination of the Term those Installations approved by Landlord in the nature of HVAC, mechanical, electrical, and plumbing systems that form an integral part of the Premises. If Landlord so elects, Tenant shall remove such Installation upon the expiration or earlier termination of this Lease and restore any damage caused by or occasioned as a result of such removal, including, when removing any of Tenant’s Property that was plumbed, wired or otherwise connected to any of the Building Systems, capping off all such connections behind the walls of the Premises and repairing any holes. During any such restoration period, Tenant shall pay Rent to Landlord as provided herein as if said space were otherwise occupied by Tenant.

(c) Lien Waivers. At Tenant’s request, Landlord shall execute and deliver commercially reasonable lien waivers in favor of Tenant’s equipment lender for Tenant’s Property located on the Premises, which lien waivers shall (i) be limited to specific items of equipment (instead of so-called “blanket” lien waivers), and (ii) , in all cases, be in the form of the lien waivers, if any, used by Landlord and its affiliates with the lender in question.

13. Landlord’s Repairs. Landlord, as an Operating Expense, shall maintain all of the structural portions of the Building (including the structural portions of the foundation, structural portions of the walls, structural portions of the floor/ceiling slabs, roof, exterior glass and mullions, columns, beams, shafts (including elevator shafts), elevators, and structural portions of the stairs), exterior, parking and other Common Areas of the Project (“Building Systems”), in good repair, reasonable wear and tear and uninsured losses and damages caused by Tenant, or by any of

Copyright © 2007, Alexandria Real Estate Equities, Inc. - Do Not Copy or Distribute. Alexandria and the Alexandria Logo are registered trademarks of Alexandria Real Estate Equities, Inc.
Tenant’s agents, servants, employees, invitees and contractors (collectively, “Tenant Parties”) excluded. Losses and damages caused by Tenant or any Tenant Party shall be repaired by Landlord, to the extent not covered by insurance, at Tenant’s sole cost and expense, subject to the terms of Section 17 below regarding each party’s waiver of subrogation. Landlord reserves the right to stop Building Systems services when necessary (i) by reason of accident or emergency, or (ii) for planned repairs, alterations or improvements, which are, in the judgment of Landlord, desirable or necessary to be made, until said repairs, alterations or improvements shall have been completed. Landlord shall have no responsibility or liability for failure to supply Building Systems services during any such period of interruption; provided, however, that Landlord shall, except in case of emergency, make a commercially reasonable effort to give Tenant 48 hours advance notice of any planned stoppage of Building Systems services for routine maintenance, repairs, alterations or improvements. Tenant shall promptly give Landlord written notice of any repair required by Landlord pursuant to this Section, after which Landlord shall have a reasonable opportunity to effect such repair. Tenant shall not be liable for any failure to make any repairs or to perform any maintenance unless such failure shall persist for an unreasonable time after Tenant’s written notice of the need for such repairs or maintenance. Tenant waives its rights under any state or local law to terminate this Lease or to make such repairs at Landlord’s expense and agrees that the parties’ respective rights with respect to such matters shall be solely as set forth herein. Repairs required as the result of fire, earthquake, flood, vandalism, war, or similar cause of damage or destruction shall be controlled by Section 18.

14. Tenant’s Repairs. Subject to Section 13 hereof, Tenant, at its expense, shall repair, replace and maintain in good condition all portions of the Premises, including, without limitation, entries, doors, ceilings, interior windows, interior walls, the interior side of demising walls, and HVAC systems serving the Premises. Such repair and replacement may include capital expenditures and repairs whose benefit may extend beyond the Term. Should Tenant fail to make any such repair or replacement or fail to maintain the Premises, Landlord shall give Tenant notice of such failure. If Tenant fails to commence cure of such failure within 10 days of Landlord’s notice, and thereafter diligently prosecute such cure to completion, Landlord may perform such work and shall be reimbursed the actual, reasonable cost thereof by Tenant within 10 days after demand therefor; provided, however, that if such failure by Tenant creates or could create an emergency, Landlord may immediately commence cure of such failure and shall thereafter be entitled to recover the actual, reasonable costs of such cure from Tenant. Subject to Sections 17 and 18, Tenant shall bear the full uninsured cost of any repair or replacement to any part of the Project that results from damage caused by Tenant or any Tenant Party and any repair that benefits only the Premises.

(a) HVAC Maintenance Contracts. Tenant, at its expense, shall, at all times during the Term maintain with qualified contractors maintenance and repair contracts (“HVAC Maintenance Contracts”) for all HVAC units serving the Premises. The HVAC Maintenance Contracts shall be in form and content reasonably satisfactory to Landlord. Landlord shall be a third party beneficiary of the HVAC Maintenance Contracts and, within 30 days after Landlord’s request, Tenant shall deliver a copy of the HVAC Maintenance Contracts to Landlord.

(b) HVAC Condition; Replacement. Within 15 days after the Commencement Date, Landlord shall obtain and provide to Tenant a copy of a report prepared by a reputable mechanical engineer evaluating the condition of the base building HVAC system serving the Premises. If the report indicates that such HVAC system is not in good operating condition, Landlord shall, at its sole cost and expense, promptly replace such HVAC system with a new HVAC system of comparable tonnage. Tenant shall thereafter maintain, repair, and replace such HVAC system as provided in this Section 14.

15. Mechanic’s Liens. Tenant shall discharge, by bond or otherwise, any mechanic’s lien filed against the Premises or against the Project for work claimed to have been done for, or materials claimed to have been furnished to, Tenant within 10 days after the filing thereof, at Tenant’s sole cost and shall otherwise keep the Premises and the Project free from any liens arising out of work performed.
materials furnished or obligations incurred by Tenant. Should Tenant fail to discharge any lien described herein, Landlord shall have the right, but not the obligation, to pay such claim or post a bond or otherwise provide security to eliminate the lien as a claim against title to the Project and the cost thereof shall be immediately due from Tenant as Additional Rent. If Tenant shall lease or finance the acquisition of office equipment, furnishings, or other personal property of a removable nature utilized by Tenant in the operation of Tenant’s business, Tenant warrants that any Uniform Commercial Code Financing Statement filed as a matter of public record by any lessor or creditor of Tenant will upon its face or by exhibit thereto indicate that such Financing Statement is applicable only to removable personal property of Tenant located within the Premises. In no event shall the address of the Project be furnished on the statement without qualifying language as to applicability of the lien only to removable personal property, located in an identified suite held by Tenant.

16. Indemnification.

(a) By Tenant. Tenant hereby indemnifies and agrees to defend, save and hold Landlord harmless from and against any and all third party Claims for injury or death to persons or damage to property occurring within or about the Premises, arising directly or indirectly out of use or occupancy of the Premises or a breach or default by Tenant in the performance of any of its obligations hereunder, except to the extent caused by the willful misconduct or negligence of Landlord or its employees. Landlord shall not be liable to Tenant for, and Tenant assumes all risk of damage to, personal property at the Premises (including, without limitation, loss of records kept within the Premises). Tenant further waives any and all Claims for injury to Tenant’s business or loss of income relating to any such damage or destruction of personal property (including, without limitation, any loss of records). Landlord shall not be liable for any damages arising from any act, omission or neglect of any tenant in the Project or of any other third party.

(b) By Landlord. Landlord hereby indemnifies and agrees to defend, save and hold Tenant harmless from and against (i) any and all Claims for injury or death to persons or damage to property occurring within or about the Project (excluding, however, the Premises) to the extent arising directly or indirectly out of a breach or default by Landlord in the performance of any of its obligations hereunder, except to the extent caused by the willful misconduct or negligence of Tenant or its employees, and (ii) any and all Claims relating to the presence of Hazardous Materials in, on, under, or about the Project before the Commencement Date ("Pre-Existing Environmental Condition"), including Claims relating to the removal or remediation of Hazardous Materials that are a Pre-Existing Environmental Condition.

17. Insurance. Landlord shall maintain all risk property and, if applicable, sprinkler damage insurance covering the full replacement cost of the Project or such lesser coverage amount as Landlord may elect provided such coverage amount is not less than [***] of such full replacement cost. Landlord shall further procure and maintain commercial general liability insurance with a single loss limit of not less than [***] for bodily injury and property damage with respect to the Project. Landlord may, but is not obligated to, maintain such other insurance and additional coverages as it may deem necessary, including, but not limited to, flood, environmental hazard and earthquake, loss or failure of building equipment, errors and omissions, rental loss during the period of repair or rebuilding, workers’ compensation insurance and fidelity bonds for employees employed to perform services and insurance for any improvements installed by Tenant or that are in addition to the standard improvements customarily furnished by Landlord without regard to whether or not such are made a part of the Project. All such insurance shall be included as part of the Operating Expenses. The Project may be included in a blanket policy (in which case the cost of such insurance allocable to the Project will be determined by Landlord based upon the insurer’s cost calculations). Tenant shall also reimburse Landlord for any increased premiums or additional insurance that Landlord reasonably deems necessary as a result of Tenant’s use of the Premises.
Tenant, at its sole cost and expense, shall maintain during the Term: all risk property insurance with business interruption and extra expense coverage, covering the full replacement cost of all property and improvements installed or placed in the Premises by Tenant at Tenant’s expense; workers’ compensation insurance with no less than the minimum limits required by law; employer’s liability insurance with such limits as required by law; and commercial general liability insurance, with a minimum limit of not less than $[***] per occurrence for bodily injury and property damage with respect to the Premises. The commercial general liability insurance policy shall name Landlord and Alexandria Real Estate Equities, Inc., and its and their respective members, officers, directors, employees, managers, and agents (collectively, “Landlord Parties”), as additional insureds; insure on an occurrence and not a claims-made basis; be issued by insurance companies that have a rating of not less than policyholder rating of A and financial category rating of at least Class VII in “Best’s Insurance Guide”; shall not be cancelable for nonpayment of premium unless 10 days prior written notice shall have been given to Landlord from the insurer; contain a hostile fire endorsement and a contractual liability endorsement; and provide primary coverage to Landlord (any policy issued to Landlord providing duplicate or similar coverage shall be deemed excess over Tenant’s policy). Copies of such policies (if requested by Landlord), or certificates of insurance (in form and substance satisfactory to Landlord; form ACORD 28 (2006/07) is not satisfactory to Landlord) showing the limits of coverage required hereunder and showing Landlord as an additional insured, along with reasonable evidence of the payment of premiums for the applicable period, shall be delivered to Landlord by Tenant upon Tenant’s execution and delivery of this Lease and upon each renewal of said insurance. Tenant’s policy may be a “blanket policy” with an aggregate per location endorsement that specifically provides that the amount of insurance shall not be prejudiced by other losses covered by the policy. Tenant shall, at least 5 days prior to the expiration of such policies, furnish Landlord with renewal certificates.

In each instance where insurance is to name Landlord as an additional insured, Tenant shall upon written request of Landlord also designate and furnish certificates so evidencing Landlord as additional insured to: (i) any lender of Landlord holding a security interest in the Project or any portion thereof, (ii) the landlord under any lease wherein Landlord is tenant of the real property on which the Project is located, if the interest of Landlord is or shall become that of a tenant under a ground or other underlying lease rather than that of a fee owner, and/or (iii) any management company retained by Landlord to manage the Project.

The property insurance obtained by Landlord and Tenant shall include a waiver of subrogation by the insurers and all rights based upon an assignment from its insured, against Landlord or Tenant, and their respective officers, directors, employees, managers, agents, invitees and contractors (“Related Parties”), in connection with any loss or damage thereby insured against. Neither party nor its respective Related Parties shall be liable to the other for loss or damage caused by any risk insured against under property insurance required to be maintained hereunder, and each party waives any claims against the other party, and its respective Related Parties, for such loss or damage. The failure of a party to insure its property shall not void this waiver. Landlord and its respective Related Parties shall not be liable for, and Tenant hereby waives all claims against such parties for, business interruption and losses occasioned thereby sustained by Tenant or any person claiming through Tenant resulting from any accident or occurrence in or upon the Premises or the Project from any cause whatsoever. If the foregoing waivers shall contravene any law with respect to exculpatory agreements, the liability of Landlord or Tenant shall be deemed not released but shall be secondary to the other’s insurer.

Landlord may require insurance policy limits to be raised to conform with requirements of Landlord’s lender and/or to bring coverage limits to levels then being generally required of new tenants within the Project, provided that such limits shall not exceed the limits being required by other owners of comparable projects in the vicinity of the Project.
18. Restoration. If, at any time during the Term, the Project or the Premises are damaged or destroyed by a fire or other insured casualty, Landlord shall notify Tenant within 60 days after discovery of such damage as to the amount of time Landlord reasonably estimates it will take to restore the Project or the Premises, as applicable (“Restoration Period”). If the Restoration Period is estimated to exceed 12 months (“Maximum Restoration Period”), Landlord may, in such notice, elect to terminate this Lease as of the date that is 75 days after the date of discovery of such damage or destruction; provided, however, that notwithstanding Landlord’s election to restore, Tenant may elect to terminate this Lease by written notice to Landlord delivered within 5 business days of receipt of a notice from Landlord estimating a Restoration Period for the Premises longer than the Maximum Restoration Period. Unless either Landlord or Tenant so elects to terminate this Lease, Landlord shall, subject to receipt of sufficient insurance proceeds (with any deductible to be treated as a current Operating Expense), promptly restore the Premises (excluding the improvements installed by Tenant or by Landlord and paid for by Tenant), subject to delays arising from the collection of insurance proceeds, from Force Majeure events or as needed to obtain any license, clearance or other authorization of any kind required to enter into and restore the Premises issued by any Governmental Authority having jurisdiction over the use, storage, handling, treatment, generation, release, disposal, removal or remediation of Hazardous Materials (as defined in Section 30) in, on or about the Premises (collectively referred to herein as “Hazardous Materials Clearances”); provided, however, that if repair or restoration of the Premises is not substantially complete as of the end of the Maximum Restoration Period or, if longer, the Restoration Period, Landlord may, in its sole and absolute discretion, elect not to proceed with such repair and restoration, or Tenant may by written notice to Landlord delivered within 5 business days of the expiration of the Maximum Restoration Period or, if longer, the Restoration Period, elect to terminate this Lease, in which event Landlord shall be relieved of its obligation to make such repairs or restoration and this Lease shall terminate as of the date that is 75 days after the later of: (i) discovery of such damage or destruction, or (ii) the date all required Hazardous Materials Clearances are obtained, but Landlord shall retain any Rent paid and the right to any Rent payable by Tenant prior to such election by Landlord or Tenant.

Tenant, at its expense, shall promptly perform, subject to delays arising from the collection of insurance proceeds, from Force Majeure (as defined in Section 18) events or to obtain Hazardous Material Clearances, all repairs or restoration not required to be done by Landlord and shall promptly re-enter the Premises and commence doing business in accordance with this Lease. Notwithstanding the foregoing, either Landlord or Tenant may terminate this Lease if the Premises are damaged during the last year of the Term and Landlord reasonably estimates that it will take more than 2 months to repair such damage, or if insurance proceeds are not available for such restoration. Rent shall be abated from the date all required Hazardous Material Clearances are obtained until the Premises are repaired and restored, in the proportion that the area of the Premises, if any, that is not usable by Tenant bears to the total area of the Premises, unless Landlord provides Tenant with other space during the period of repair that is suitable for the temporary conduct of Tenant’s business (in Tenant’s reasonable discretion). Such abatement shall be the sole remedy of Tenant, and except as provided in this Section 18, Tenant waives any right to terminate this Lease by reason of damage or casualty loss.

The provisions of this Lease, including this Section 18, constitute an express agreement between Landlord and Tenant with respect to any and all damage to, or destruction of, all or any part of the Premises, or any other portion of the Project, or any statute or regulation that is now or may hereafter be in effect shall have no application to this Lease or any damage or destruction to all or any part of the Premises or any other portion of the Project, the parties hereto expressly agreeing that this Section 18 sets forth their entire understanding and agreement with respect to such matters.

19. Condemnation. If the whole or any material part of the Premises or the Project is taken for any public or quasi-public use under governmental law, ordinance, or regulation, or by right of eminent domain, or by private purchase in lieu thereof (a “Taking” or “Taken”), and the Taking would either prevent or materially interfere with Tenant’s use of the Premises or materially interfere with or impair Landlord’s ownership or operation of the Project, then upon written notice by Landlord or Tenant to the other party this Lease shall terminate and Rent shall be apportioned as of said date. If part of the...
Premises shall be Taken, and this Lease is not terminated as provided above, Landlord shall promptly restore the Premises and the Project as nearly as is commercially reasonable under the circumstances to their condition prior to such partial Taking and the rentable square footage of the Building, the rentable square footage of the Premises, Tenant's Share of Operating Expenses and the Rent payable hereunder during the unexpired Term shall be reduced to such extent as may be fair and reasonable under the circumstances. Upon any such Taking, Landlord shall be entitled to receive the entire price or award from any such Taking without any payment to Tenant, and Tenant hereby assigns to Landlord Landlord’s interest, if any, in such award. Tenant shall have the right, to the extent that same shall not diminish Landlord’s award, to make a separate claim against the condemning authority (but not Landlord) for such compensation as may be separately awarded or recoverable by Tenant for moving expenses and damage to improvements paid for by Tenant and Tenant's trade fixtures, if a separate award for such items is made to Tenant. Tenant hereby waives any and all rights it might otherwise have pursuant to any provision of state law to terminate this Lease upon a partial Taking of the Premises or the Project.

20. Events of Default. Each of the following events shall be a default ("Default") by Tenant under this Lease:

(a) Payment Defaults. Tenant shall fail to pay any installment of Rent or any other payment hereunder within 5 days of written notice of default from Landlord.

(b) Insurance. Any insurance required to be maintained by Tenant pursuant to this Lease shall be canceled or terminated or shall expire or shall be reduced or materially changed, or Landlord shall receive a notice of nonrenewal of any such insurance and Tenant shall fail to obtain replacement insurance before the expiration of the current coverage.

(c) Abandonment. Tenant shall abandon the Premises without (i) the release of the Premises of all Hazardous Materials Clearances and free of any residual impact from the Tenant HazMat Operations, and (ii) complying with the provisions of Section 28.

(d) Improper Transfer. Tenant shall assign, sublease or otherwise transfer or attempt to transfer all or any portion of Tenant’s interest in this Lease or the Premises except as expressly permitted herein, or Tenant’s interest in this Lease shall be attached, executed upon, or otherwise judicially seized and such action is not released within 90 days of the action.

(e) Liens. Tenant shall fail to discharge or otherwise obtain the release of any lien placed upon the Premises in violation of this Lease within 10 days after any such lien is filed against the Premises.

(f) Insolvency Events. Tenant or any guarantor or surety of Tenant’s obligations hereunder shall: (A) make a general assignment for the benefit of creditors; (B) commence any case, proceeding or other action seeking to have an order for relief entered on its behalf as a debtor or to adjudicate it a bankrupt or insolvency, or seeking reorganization, arrangement, adjustment, liquidation, dissolution or composition of it or its debts or seeking the appointment of a receiver, trustee, custodian or other similar official for it or for all or any substantial part of its property (collectively a “Proceeding for Relief’); (C) become the subject of any Proceeding for Relief that is not dismissed within 90 days of its filing or entry; or (D) die or suffer a legal disability (if Tenant, guarantor, or surety is an individual) or be dissolved or otherwise fail to maintain its legal existence (if Tenant, guarantor or surety is a corporation, partnership or other entity).

(g) Estoppel Certificate or Subordination Agreement. Tenant fails to execute any document required from Tenant under Sections 23 or 27 within 5 business days after a second notice requesting such document.
(h) **Other Defaults.** Tenant shall fail to comply with any provision of this Lease other than those specifically referred to in this Section 20, and, except as otherwise expressly provided herein, such failure shall continue for a period of 15 days after written notice thereof from Landlord to Tenant. Any notice given under Section 20(h) hereof shall: (i) specify the alleged default, (ii) demand that Tenant cure such default, (iii) be in lieu of, and not in addition to, or shall be deemed to be, any notice required under any provision of applicable law, and (iv) not be deemed a forfeiture or a termination of this Lease unless Landlord elects otherwise in such notice; provided that if the nature of Tenant’s default pursuant to Section 20(h) is such that it cannot be cured by the payment of money and reasonably requires more than 15 days to cure, then Tenant shall not be deemed to be in default if Tenant commences such cure within said 15 day period and thereafter diligently prosecutes the same to completion; provided, however, that such cure shall be completed no later than 90 days from the date of Landlord’s notice.

21. **Landlord’s Remedies.**

(a) **Interest.** Upon a Default by Tenant hereunder, Landlord may, without waiving or releasing any obligation of Tenant hereunder, make such payment or perform such act. All sums so paid or incurred by Landlord, together with interest thereon, from the date such sums were paid or incurred, at the annual rate equal to [***]% per annum or the highest rate permitted by law ("Default Rate"), whichever is less, shall be payable to Landlord on demand as Additional Rent. Except as provided in Section 21(g) below, nothing herein shall be construed to create or impose a duty on Landlord to mitigate any damages resulting from Tenant’s Default hereunder.

(b) **Late Payment Rent.** Late payment by Tenant to Landlord of Rent and other sums due will cause Landlord to incur costs not contemplated by this Lease, the exact amount of which will be extremely difficult and impracticable to ascertain. Such costs include, but are not limited to, processing and accounting charges and late charges that may be imposed on Landlord under any Mortgage covering the Premises. Therefore, if any installment of Rent due from Tenant is not received by Landlord within 5 days after the date such payment is due, Tenant shall pay to Landlord an additional sum of 5% of the overdue Rent as a late charge (provided that Tenant shall not be required to pay such late charge upon the first occurrence of a late payment by Tenant of Rent). The parties agree that this late charge represents a fair and reasonable estimate of the costs Landlord will incur by reason of late payment by Tenant. In addition to the late charge, Rent not paid when due shall bear interest at the Default Rate from the 5th day after the date due until paid.

(c) **Re-Entry.** Landlord shall have the right, immediately or at any time thereafter, without further notice to Tenant (unless otherwise provided herein), to enter the Premises, without terminating this Lease or being guilty of trespass, and do any and all acts as Landlord may deem necessary, proper or convenient to cure such default, for the account and at the expense of Tenant, any notice to quit or notice of Landlord’s intention to re-enter being hereby expressly waived, and Tenant agrees to pay to Landlord as Additional Rent all damage and/or expense incurred by Landlord in so doing, including interest at the Default Rate, from the due date until the date payment is received by Landlord.

(d) **Termination.** Landlord shall have the right to terminate this Lease and Tenant’s right to possession of the Premises and, in accordance with applicable Legal Requirements, take possession of the Premises and remove Tenant, any occupant and any property therefrom, without being guilty of trespass and without relinquishing any rights of Landlord against Tenant, any notice to quit, or notice of Landlord’s intention to re-enter being hereby expressly waived. Landlord shall be entitled to recover damages from Tenant for all amounts covenant to be paid during the remainder of the Term (except for the period of any holdover by Tenant, in which case the monthly rental rate stated at Section 8 herein shall apply), which may be accelerated by Landlord at its option to the present value of the amounts owed (which discount to present value shall be made in accordance with accepted financial practice using a rate of [***]% per annum), together with (i) all expenses of any proceedings (including, but not limited to, the
expenses set forth in Section 11(e) below) that may be necessary in order for Landlord to recover possession of the Premises, (ii) the expenses of the re-renting of the Premises (including, but not limited to, any commissions paid to any real estate agent, advertising expense and the costs of such alterations, repairs, replacements or modifications that Landlord, in its sole judgment, considers advisable and necessary for the purpose of re-renting), in each case prorated based on the remaining length of the Term, and (iii) interest computed at the Default Rate from the due date until paid; provided, however, that there shall be credited against the amount of such damages all amounts received by Landlord from such re-renting of the Premises, with any overage being refunded to Tenant (or, if Landlord has elected to accelerate the amounts due, then Tenant shall have the right to deduct the present value of the amount for which Landlord, in its reasonable determination, should reasonably be able to relet the Premises). Landlord shall in no event be liable in any way whatsoever for failure to re-rent the Premises or, in the event that the Premises are re-rented, for failure to collect the rent thereof under such re-renting and, except as provided in Section 21(e) below, Tenant expressly waives any duty of the Landlord to mitigate damages. No act or thing done by Landlord shall be deemed to be an acceptance of a surrender of the Premises, unless Landlord shall execute a written agreement of surrender with Tenant. Tenant’s liability hereunder shall not be terminated by the execution of a new lease of the Premises by Landlord, unless that new lease expressly so states. In the event Landlord does not exercise its option to accelerate the payment of amounts owed as provided hereinabove, then Tenant agrees to pay to Landlord, upon demand, the amount of damages herein provided after the amount of such damages for any month shall have been ascertained; provided, however, that any expenses incurred by Landlord shall be deemed to be a part of the damages for the month in which they were incurred. Separate actions may be maintained each month or at other times by Landlord against Tenant to recover the damages then due, without waiting until the end of the term of this Lease to determine the aggregate amount of such damages. Tenant hereby expressly waives any and all rights of redemption granted by or under any present or future laws in the event of Tenant being evicted or being dispossessed for any cause, or in the event of Landlord obtaining possession of the Premises by reason of the violation by Tenant of any of the covenants and conditions of this Lease.

(e) Suspension of Funding/Performance. Upon a Default by Tenant hereunder and during the continuance thereof, Landlord shall have the right to suspend funding of any TI Allowance or the performance of Landlord’s Work (and such suspension shall constitute a Tenant Delay [as defined in Exhibit C-1 attached hereto]).

(f) Other Remedies. In addition to the remedies set forth in this Section 21, Landlord, at its option, without further notice or demand to Tenant, shall have all other rights and remedies provided at law or in equity.

(g) Mitigation. Nothing herein shall be construed to create or impose a duty on Landlord to mitigate any damages resulting from Tenant’s Default hereunder; provided, however, that to the extent required by applicable Legal Requirements, each party shall use commercially reasonable efforts to mitigate its damages in the event of a default or breach hereunder by the other party.

22. Assignment and Subletting.

(a) General Prohibition. Without Landlord’s prior written consent subject to and on the conditions described in this Section 22, Tenant shall not, directly or indirectly, voluntarily or by operation of law, assign this Lease or sublease the Premises or any part thereof or mortgage, pledge, or hypothecate its leasehold interest or grant any concession or license within the Premises, and any attempt to do any of the foregoing shall be void and of no effect. If Tenant is a corporation, partnership or limited liability company, the shares or other ownership interests thereof that are not actively traded upon a stock exchange or in the over-the-counter market, a transfer or series of transfers whereby 49% or more of the issued and outstanding shares or other ownership interests of such corporation are, or voting control is, transferred (but excepting transfers upon deaths of individual owners) from a person or persons

Copyright © 2007, Alexandria Real Estate Equities, Inc.
ALL RIGHTS RESERVED. Confidential and Proprietary - Do Not Copy or Distribute. Alexandria and the Alexandria Logo are registered trademarks of Alexandria Real Estate Equities, Inc.
or entity or entities that were owners thereof at time of execution of this Lease to persons or entities who were not owners of shares or other ownership interests of the corporation, partnership or limited liability company at time of execution of this Lease, shall be deemed an assignment of this Lease requiring the consent of Landlord as provided in this Section 22. Notwithstanding the foregoing, any public offering of shares or other ownership interest in Tenant shall not be deemed an assignment.

(b) Permitted Transfers. If Tenant desires to assign, sublease, hypothecate or otherwise transfer this Lease or sublet the Premises other than pursuant to a Permitted Assignment (as defined below), then at least 15 business days, but not more than 45 business days, before the date Tenant desires the assignment or sublease to be effective (“Assignment Date”), Tenant shall give Landlord a notice (“Assignment Notice”) containing such information about the proposed assignee or sublessee, including the proposed use of the Premises and any Hazardous Materials proposed to be used, stored, handled, treated, generated in or released or disposed of from the Premises, the Assignment Date, any relationship between Tenant and the proposed assignee or sublessee, and all material terms and conditions of the proposed assignment or sublease, including a copy of any proposed assignment or sublease in its final form, and such other information as Landlord may deem reasonably necessary or appropriate to its consideration whether to grant its consent. Landlord may, by giving written notice to Tenant within 10 business days after receipt of the Assignment Notice: (i) grant such consent, or (ii) refuse such consent, in its reasonable discretion (provided that Landlord shall further have the right to review and approve or disapprove the proposed form of sublease prior to the effective date of any such subletting). Tenant shall pay to Landlord a fee equal to $1,500 in connection with its consideration of any Assignment Notice and/or its preparation or review of any consent documents.

Tenant shall have the right to assign this Lease, upon 30 days prior written notice to Landlord but without obtaining Landlord’s prior written consent, to a corporation or other entity that is a successor-in-interest to Tenant, by way of merger, consolidation or corporate reorganization, or by the purchase of all or substantially all of the assets or the ownership interests of Tenant provided that (i) such merger or consolidation, or such acquisition or assumption, as the case may be, is for a good business purpose and not principally for the purpose of transferring this Lease, and (ii) the net worth (as determined in accordance with generally accepted accounting principles (“GAAP”)) of the assignee is not less than the net worth (as determined in accordance with GAAP) of Tenant as of the date of Tenant’s most current quarterly or annual financial statements, and (iii) such assignee shall agree in writing to assume all of the terms, covenants and conditions of this Lease arising after the effective date of the assignment (a “Permitted Assignment”).

(c) Additional Conditions. As a condition to any such assignment or subletting, whether or not Landlord’s consent is required, Landlord may require:

(i) that any assignee or subtenant agree, in writing at the time of such assignment or subletting, that if Landlord gives such party notice that Tenant is in default under this Lease, such party shall thereafter make all payments otherwise due Tenant directly to Landlord, which payments will be received by Landlord without any liability except to credit such payment against those due under this Lease, and any such third party shall agree to attorn to Landlord or its successors and assigns should this Lease be terminated for any reason; provided, however, in no event shall Landlord or its successors or assigns be obligated to accept such attornment; and

(ii) A list of Hazardous Materials, certified by the proposed assignee or sublessee to be true and correct, which the proposed assignee or sublessee intends to use, store, handle, treat, generate in or release or dispose of from the Premises, together with copies of all documents relating to such use, storage, handling, treatment, generation, release or disposal of Hazardous Materials by the proposed assignee or subtenant in the Premises or on the Project, prior to the proposed assignment or subletting, including, without limitation: permits,
approvals; reports and correspondence; storage and management plans; plans relating to the installation of any storage tanks to be installed
in or under the Project (provided, said installation of tanks shall only be permitted after Landlord has given its written consent to do so,
which consent may be withheld in Landlord’s sole and absolute discretion); and all closure plans or any other documents required by any
and all federal, state and local Governmental Authorities for any storage tanks installed in, on or under the Project for the closure of any
such tanks. Neither Tenant nor any such proposed assignee or subtenant is required, however, to provide Landlord with any portion(s) of
the such documents containing information of a proprietary nature that, in and of themselves, do not contain a reference to any Hazardous
Materials or hazardous activities.

(d) No Release of Tenant, Sharing of Excess Rents. Notwithstanding any assignment or subletting, Tenant and any guarantor or surety of
Tenant’s obligations under this Lease shall at all times remain fully and primarily responsible and liable for the payment of Rent and for compliance
with all of Tenant’s other obligations under this Lease; provided, however, that the initial Tenant hereunder (i.e., Kite Pharma, Inc., shall have no
responsibility or liability for such payment and compliance obligations under this Lease first arising from and after the date of a Permitted Assignment
of this Lease to the initial Tenant’s parent, Gilead Sciences, Inc., a Delaware corporation. If the Rent due and payable by a sublessee or assignee (or a
combination of the rental payable under such sublease or assignment plus any bonus or other consideration therefor or incident thereto in any form)
exceeds the sum of the rental payable under this Lease (excluding, however, any Rent payable under this Section and actual and reasonable brokerage
fees, legal costs, any design or construction fees directly related to and required pursuant to the terms of any such sublease, and the unamortized cost of
any improvements (calculated on a straight-line basis over the useful life of the improvement in question) made to the subleased area paid for by Tenant
outside of the TI Allowance (“Excess Rent”)), then Tenant shall be bound and obligated to pay Landlord as Additional Rent hereunder 50% of such
Excess Rent within 10 days following receipt thereof by Tenant; provided, however, that Tenant’s obligation to pay Excess Rent in connection with a
sublease or assignment shall not apply to any sublease or assignment made pursuant to a Permitted Assignment. If Tenant shall sublet the Premises or
any part thereof, Tenant hereby immediately and irrevocably assigns to Landlord, as security for Tenant’s obligations under this Lease, all rent from any
such subletting, and Landlord may collect such rent and apply it toward Tenant’s obligations under this Lease; except that, until the occurrence of a
Default, Tenant shall have the right to collect such rent. Notwithstanding the foregoing, Tenant may convey, in connection with an assignment or
subletting, but pursuant to a separate legally binding agreement, Tenant’s non-real property assets, goodwill, intellectual property, business and trade
fixtures, inventory, equipment, or furniture as well as all other Tenant’s Property to the extent paid for by Tenant (“Tenant’s FF&E”), and Tenant shall
be entitled to retain any and all consideration received in connection with such conveyance to the extent such consideration does not exceed the fair
market value of Tenant’s FF&E.

(e) No Waiver. The consent by Landlord to an assignment or subletting shall not relieve Tenant or any assignees of this Lease or any sublessees of
the Premises from obtaining the consent of Landlord to any further assignment or subletting nor shall it release Tenant or any assignee or sublessee of
Tenant from full and primary liability under this Lease. The acceptance of Rent hereunder, or the acceptance of performance of any other term,
covenant, or condition thereof, from any other person or entity shall not be deemed to be a waiver of any of the provisions of this Lease or a consent to
any subletting, assignment or other transfer of the Premises.

(f) Prior Conduct of Proposed Transferee. Notwithstanding any other provision of this Section 22, if the proposed assignee or sublessee of
Tenant has been required by any prior landlord, lender or Governmental Authority to take remedial action in connection with Hazardous Materials
contaminating a property, where the contamination resulted from such party’s action or use of the

Copyright © 2007, Alexandria Real Estate Equities, Inc.
ALL RIGHTS RESERVED. Confidential and Proprietary -
Do Not Copy or Distribute. Alexandria and the Alexandria
Logo are registered trademarks of Alexandria Real Estate
Equities, Inc.
property in question, (ii) the proposed assignee or sublessee is subject to an enforcement order issued by any Governmental Authority in connection with the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials (including, without limitation, any order related to the failure to make a required reporting to any Governmental Authority), or (iii) because of the existence of a pre-existing environmental condition in the vicinity of or underlying the Project, the risk that Landlord would be targeted as a responsible party in connection with the remediation of such pre-existing environmental condition would be materially increased or exacerbated by the proposed use of Hazardous Materials by such proposed assignee or sublessee, Landlord shall have the absolute right to refuse to consent to any assignment or subletting to any such party.

(g) Business Entity Occupancy. Tenant shall have the right, upon 30 days prior written notice to Landlord but without obtaining Landlord’s prior written consent, to permit a business entity that is a contractor of Tenant (or an entity for whom Tenant is a subcontractor), collaborator, affiliate, subsidiary, client, customer, co-developer, or otherwise has a business relationship with Tenant, and is providing Tenant services in the course of Tenant’s business operations at the Premises or is occupying the Building in furtherance of such business relationship with Tenant (a “Business Entity” or “Business Entities”) to use not more than 5,000 rentable square feet of the Premises for any Permitted Use; provided, however, that (i) Tenant receives no compensation for such use in excess of that portion of the Rent attributable to such portion of the Premises, (ii) the entity remains a Business Entity for the entire duration of such use and the entity is not indicated on the Building directory or any signage on the Premises (“Business Entity Occupancy”), (iii) no new demising walls are constructed to accomplish the Business Entity Occupancy, (iv) Tenant shall be responsible for any and all claims arising out of or in connection with the Business Entity Occupancy or any act or omission of any Business Entity, and Tenant shall indemnify, defend, hold and save Landlord harmless from and against any and all Claims arising out of or in connection with any Business Entity Occupancy or any act or omission of any Business Entity, and (v) the provisions of this paragraph are personal to Kite Pharma, Inc. and the transferee under any Permitted Assignment. Such Business Entity Occupancy shall not be deemed a sublease or assignment hereunder, nor shall it vest in any such Business Entity any right, title, or interest in this Lease or the Premises nor shall it relieve, release, impair, or discharge any of Tenant’s obligations hereunder. Tenant shall ensure that the Business Entity complies with the terms of this Lease. A failure or breach of any term, covenant, condition, or other provision of this Lease by any Business Entity shall constitute a breach of such term, covenant, condition, or other provision of this Lease by Tenant and, if such failure or breach is not cured within any applicable notice and cure period under this Lease, shall constitute a Default by Tenant.

23. Estoppel Certificate. Tenant shall, within 10 business days of written notice from Landlord, execute, acknowledge and deliver a statement in writing in any form reasonably requested by a proposed lender or purchaser, (i) certifying that this Lease is unmodified and in full force and effect (or, if modified, stating the nature of such modification and certifying that this Lease as so modified is in full force and effect) and the dates to which the rental and other charges are paid in advance, if any, (ii) acknowledging that to the actual knowledge of Tenant there are not any uncured defaults on the part of Landlord hereunder, or specifying such defaults if any are claimed, and (iii) setting forth such further information with respect to the status of this Lease or the Premises as may be requested thereon. Any such statement may be relied upon by any prospective purchaser or encumbrancer of all or any portion of the real property of which the Premises are a part. Tenant’s failure to deliver such statement within such time shall, at the option of Landlord, be conclusive upon Tenant that this Lease is in full force and effect and without modification except as may be represented by Landlord in any certificate prepared by Landlord and delivered to Tenant for execution.

24. Quiet Enjoyment. So long as Tenant shall perform all of the covenants and agreements herein required to be performed by Tenant, Tenant shall, subject to the terms of this Lease, at all times during the Term, have peaceful and quiet enjoyment of the Premises against any person claiming by, through or under Landlord.
25. Prorations. All prorations required or permitted to be made hereunder shall be made on the basis of a 360 day year and 30 day months.

26. Rules and Regulations. Tenant shall, at all times during the Term and any extension thereof, comply with all reasonable rules and regulations at any time or from time to time established by Landlord covering use of the Premises and the Project. The current rules and regulations are attached hereto as Exhibit E. If there is any conflict between said rules and regulations and other provisions of this Lease, the terms and provisions of this Lease shall control. Landlord shall not have any liability or obligation for the breach of any rules or regulations by other tenants in the Project and shall not enforce such rules and regulations in a discriminatory manner.

27. Subordination. As of the Commencement Date, the Project and the Premises are not encumbered by a Mortgage. This Lease and Tenant’s interest and rights hereunder are hereby made and shall be subject and subordinate at all times to the lien of any Mortgage hereafter created on or against the Project or the Premises, and all amendments, restatements, renewals, modifications, consolidations, refinancing, assignments and extensions thereof, without the necessity of any further instrument or act on the part of Tenant; provided, however that so long as there is no Default hereunder, Tenant’s right to possession of the Premises shall not be disturbed by the Holder of any such Mortgage. Tenant agrees, at the election of the Holder of any such Mortgage, to attorn to any such Holder. Tenant agrees upon demand to execute, acknowledge and deliver such instruments, confirming such subordination, and such instruments of attornment as shall be requested by any such Holder; provided any such instruments contain appropriate non-disturbance provisions assuring Tenant’s quiet enjoyment of the Premises as set forth in Section 24 hereof. Notwithstanding the foregoing, any such Holder may at any time subordinate its Mortgage to this Lease, without Tenant’s consent, by notice in writing to Tenant, and thereupon this Lease shall be deemed prior to such Mortgage without regard to their respective dates of execution, delivery or recording and in that event such Holder shall have the same rights with respect to this Lease as though this Lease had been executed prior to the execution, delivery and recording of such Mortgage and had been assigned to such Holder. On Tenant’s written request, Landlord shall obtain from any Holder of a first lien Mortgage at any time during the Term covering any or all of the Project or the Premises a non-disturbance agreement on Holder’s standard form in favor of Tenant assuring Tenant’s quiet enjoyment of the Premises as set forth in Section 24 hereof. The term “Mortgage” whenever used in this Lease shall be deemed to include deeds of trust, security assignments and any other encumbrances, and any reference to the “Holder” of a Mortgage shall be deemed to include the beneficiary under a deed of trust.

28. Surrender. Upon the expiration of the Term or earlier termination of Tenant’s right of possession, Tenant shall surrender the Premises to Landlord in the same condition as received, subject to any Alterations or Installations permitted by Landlord to remain in the Premises, free of Hazardous Materials brought upon, kept, used, stored, handled, treated, generated in, or released or disposed of from, the Premises by any person other than a Landlord Party (collectively, “Tenant HazMat Operations”) and released of all Hazardous Materials Clearances, broom clean, ordinary wear and tear and casualty loss and condemnation covered by Sections 18 and 19 excepted. At least 3 months prior to the surrender of the Premises, Tenant shall deliver to Landlord a narrative description of the actions proposed (or required by any Governmental Authority) to be taken by Tenant in order to surrender the Premises (including any Installations permitted by Landlord to remain in the Premises) at the expiration or earlier termination of the Term, in the condition required by this Lease (“Surrender Plan”). Such Surrender Plan shall be accompanied by a current listing of (i) all Hazardous Materials licenses and permits held by or on behalf of any Tenant Party with respect to the Premises, and (ii) all Hazardous Materials used, stored, handled, treated, generated, released or disposed of from the Premises, and shall be subject to the review and approval of Landlord’s environmental consultant. In connection with the review and approval of the Surrender Plan, upon the request of Landlord, Tenant shall deliver to Landlord or its consultant such additional non-proprietary information concerning Tenant HazMat Operations as Landlord shall request. On or before such surrender, Tenant shall deliver to Landlord evidence that the

Copyright © 2007, Alexandria Real Estate Equities, Inc.
ALL RIGHTS RESERVED. Confidential and Proprietary - Do Not Copy or Distribute. Alexandria and the Alexandria Logo are registered trademarks of Alexandria Real Estate Equities, Inc.
approved Surrender Plan shall have been satisfactorily completed and Landlord shall have the right, subject to reimbursement at Tenant’s expense as set forth below, to cause Landlord’s environmental consultant to inspect the Premises and perform such additional procedures as may be deemed reasonably necessary to confirm that the Premises are, as of the effective date of such surrender or early termination of this Lease, free from any residual impact from Tenant HazMat Operations. Tenant shall reimburse Landlord, as Additional Rent, for the actual out-of-pocket expense incurred by Landlord for Landlord’s environmental consultant to review and approve the Surrender Plan and to visit the Premises and verify satisfactory completion of the same, which cost shall not exceed $5,000. Landlord shall have the unrestricted right to deliver such Surrender Plan and any report by Landlord’s environmental consultant with respect to the surrender of the Premises to third parties.

If Tenant shall fail to prepare or submit a Surrender Plan approved by Landlord, or if Tenant shall fail to complete the approved Surrender Plan, or if such Surrender Plan, whether or not approved by Landlord, shall fail to adequately address any residual effect of Tenant HazMat Operations in, on or about the Premises, Landlord shall have the right to take such actions as Landlord may deem reasonable or appropriate to assure that the Premises and the Project are surrendered free from any residual impact from Tenant HazMat Operations, the cost of which actions shall be reimbursed by Tenant as Additional Rent, without regard to the limitation set forth in the first paragraph of this Section 28.

Tenant shall immediately return to Landlord all keys and/or access cards to parking, the Project, restrooms or all or any portion of the Premises furnished to or otherwise procured by Tenant. If any such access card or key is lost, Tenant shall pay to Landlord, at Landlord’s election, either the cost of replacing such lost access card or key or the cost of reprogramming the access security system in which such access card was used or changing the lock or locks opened by such lost key. Any Tenant’s Property, Alterations and property not so removed by Tenant as permitted or required herein shall be deemed abandoned and may be stored, removed, and disposed of by Landlord at Tenant’s expense, and Tenant waives all claims against Landlord for any damages resulting from Landlord’s retention and/or disposition of such property. All obligations of Tenant hereunder not fully performed as of the termination of the Term, including the obligations of Tenant under Section 30 hereof, shall survive the expiration or earlier termination of the Term, including, without limitation, indemnity obligations, payment obligations with respect to Rent and obligations concerning the condition and repair of the Premises.

29. Waiver of Jury Trial. TENANT AND LANDLORD WAIVE ANY RIGHT TO TRIAL BY JURY OR TO HAVE A JURY PARTICIPATE IN RESOLVING ANY DISPUTE, WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE, BETWEEN LANDLORD AND TENANT ARISING OUT OF THIS LEASE OR ANY OTHER INSTRUMENT, DOCUMENT, OR AGREEMENT EXECUTED OR DELIVERED IN CONNECTION HEREWITH OR THE TRANSACTIONS RELATED HERETO.

30. Environmental Requirements.

(a) Prohibition/Compliance/Indemnity. Tenant shall not cause or permit any Hazardous Materials (as hereinafter defined) to be brought upon, kept, used, handled, treated, generated in or about, or released or disposed of from, the Premises or the Project in violation of applicable Environmental Requirements (as hereinafter defined) by Tenant or any Tenant Party. If Tenant breaches the obligation stated in the preceding sentence, or if the presence of Hazardous Materials in the Premises during the Term or any holding over results in contamination of the Premises, the Project or any adjacent property or if contamination of the Premises, the Project or any adjacent property by Hazardous Materials brought into, kept, used, stored, handled, treated, generated in or about, or released or disposed of from, the Premises by anyone other than Landlord and Landlord’s employees, agents and contractors otherwise occurs during the Term or any holding over, Tenant hereby indemnifies and shall defend and hold Landlord, its officers, directors, employees, agents and contractors harmless from any and all actions (including, without limitation, remedial or enforcement actions of any kind, administrative or judicial proceedings, and orders or judgments arising out of or resulting therefrom), costs, claims,
damages (including, without limitation, punitive damages and damages based upon diminution in value of the Premises or the Project, or the loss of, or restriction on, use of the Premises or any portion of the Project), expenses (including, without limitation, attorneys’, consultants’ and experts’ fees, court costs and amounts paid in settlement of any claims or actions), fines, forfeitures or other civil, administrative or criminal penalties, injunctive or other relief (whether or not based upon personal injury, property damage, or contamination of, or adverse effects upon, the environment, water tables or natural resources), liabilities or losses (collectively, “Environmental Claims”) that arise during or after the Term as a result of such contamination, provided, however, that Tenant shall have no indemnification, remediation, or other obligation or responsibility under this Section 30 for any contamination or Environmental Claim if Tenant proves by a preponderance of the evidence that such contamination or Environmental Claim arises from any Hazardous Materials brought into, kept, used, stored, handled, treated, generated in or about, or released or disposed of from the Premises by Landlord, its employees or contractors, or another tenant unrelated or unaffiliated with Tenant or that existed in the Premises as of the Commencement Date and were not brought into, kept, used, stored, handled, treated, generated in or about, or released or disposed of from the Premises by Tenant or any Tenant Party. This indemnification of Landlord by Tenant includes, without limitation, costs incurred in connection with any investigation of site conditions or any cleanup, treatment, remedial, removal, or restoration work required by any federal, state or local Governmental Authority because of Hazardous Materials present in the air, soil or ground water above, on, or under the Premises. Without limiting the foregoing, if the presence of any Hazardous Materials on the Premises, the Project, or any adjacent property caused or permitted by Tenant or any Tenant Party results in any contamination of the Premises, the Project, or any adjacent property, Tenant shall promptly take all actions at its sole expense and in accordance with applicable Environmental Requirements as are necessary to return the Premises, the Project, or any adjacent property to the condition existing prior to the time of such contamination, provided that Landlord’s approval of such action shall first be obtained, which approval shall not reasonably be withheld so long as such actions would not potentially have any material adverse long-term or short-term effect on the Premises or the Project.

(i) Remediation of Pre-Existing Environmental Condition. Landlord shall, at no expense to Tenant, remediate any Pre-Existing Environmental Condition in the Premises as required by applicable Legal Requirements that Tenant proves by a preponderance of the evidence is a Pre-Existing Environmental Condition.

(b) Business. Landlord acknowledges that it is not the intent of this Section 30 to prohibit Tenant from using the Premises for the Permitted Use. Tenant may operate its business according to prudent industry practices so long as the use or presence of Hazardous Materials is strictly and properly monitored according to all then applicable Environmental Requirements. As a material inducement to Landlord to allow Tenant to use Hazardous Materials in connection with its business, Tenant agrees to deliver to Landlord prior to the Commencement Date a list identifying each type of Hazardous Materials to be brought upon, kept, used, stored, handled, treated, generated on, or released or disposed of from, the Premises and setting forth any and all governmental approvals or permits required in connection with the presence, use, storage, handling, treatment, generation, release or disposal of such Hazardous Materials on or from the Premises (“Hazardous Materials List”). Tenant shall deliver to Landlord an updated Hazardous Materials List at least once a year upon request of Landlord and shall also deliver an updated list before any new Hazardous Material is brought onto, kept, used, stored, handled, treated, generated on, or released or disposed of from, the Premises and setting forth any and all governmental approvals or permits required in connection with the presence, use, storage, handling, treatment, generation, release or disposal of such Hazardous Materials on or from the Premises (“Hazardous Materials List”). Tenant shall deliver to Landlord an updated Hazardous Materials List at least once a year upon request of Landlord and shall also deliver an updated list before any new Hazardous Material is brought onto, kept, used, stored, handled, treated, generated on, or released or disposed of from, the Premises and setting forth any and all governmental approvals or permits required in connection with the presence, use, storage, handling, treatment, generation, release or disposal of such Hazardous Materials on or from the Premises (“Hazardous Materials List”). Tenant shall deliver to Landlord an updated Hazardous Materials List at least once a year upon request of Landlord and shall also deliver an updated list before any new Hazardous Material is brought onto, kept, used, stored, handled, treated, generated on, or released or disposed of from, the Premises and setting forth any and all governmental approvals or permits required in connection with the presence, use, storage, handling, treatment, generation, release or disposal of Hazardous Materials prior to the Commencement Date, if unavailable at that time, concurrent with the receipt from or submission to a Governmental Authority: permits, approvals, reports and correspondence; storage and management plans, notice of violations of any Legal Requirements, plans relating to the installation of any storage tanks to be installed in or under the Project (provided, said installation of tanks shall only be permitted after Landlord has given Tenant its written consent to do so, which consent may be withheld in Landlord’s sole and absolute discretion), all closure plans or any other documents required by any and all federal, state and local Governmental
Authorities for any storage tanks installed in, on or under the Project for the closure of any such tanks; and a Surrender Plan (to the extent surrender in accordance with Section 28 cannot be accomplished in 3 months). Tenant is not required, however, to provide Landlord with any portion(s) of the Haz Mat Documents containing information of a proprietary nature that, in and of themselves, do not contain a reference to any Hazardous Materials or hazardous activities. It is not the intent of this Section to provide Landlord with information that could be detrimental to Tenant’s business should such information become possessed by Tenant’s competitors.

(c) Tenant Representation and Warranty. Tenant hereby represents and warrants to Landlord that (i) neither Tenant nor any of its legal predecessors has been required by any prior landlord, lender, or Governmental Authority at any time to take remedial action in connection with Hazardous Materials contaminating a property, which contamination was permitted by Tenant of such predecessor or resulted from Tenant’s or such predecessor’s action or use of the property in question, and (ii) Tenant is not subject to any enforcement order issued by any Governmental Authority in connection with the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials (including, without limitation, any order related to the failure to make a required reporting to any Governmental Authority). If Landlord determines that this representation and warranty was not true as of the date of this lease, Landlord shall have the right to terminate this Lease in Landlord’s sole and absolute discretion.

(d) Testing. Landlord shall have access to, and a right to perform inspections and tests of, the Premises and the Project to determine Tenant’s compliance with Environmental Requirements (as defined below), its obligations under this Section 30 or the environmental condition of the Premises and the Project. In connection with such testing, upon the request of Landlord, Tenant shall deliver to Landlord or its consultant such non-proprietary information concerning the use of Hazardous Materials in or about the Premises by Tenant or any Tenant Party. Access shall be granted to Landlord upon Landlord’s prior notice to Tenant and at such times so as to minimize, so far as may be reasonable under the circumstances, any disturbance to Tenant’s operations. Such inspections and tests shall be conducted at Landlord’s expense, unless such inspections or tests are conducted pursuant to Section 21 hereof or reveal that Tenant has not complied with any Environmental Requirement, in which case Tenant shall reimburse Landlord for the reasonable cost of such inspection and tests. Tenant shall, at its sole cost and expense, promptly and satisfactorily remediate any environmental conditions identified by such testing in accordance with all Environmental Requirements. Landlord’s receipt of or satisfaction with any environmental assessment in no way waives any rights that Landlord may have against Tenant.

(e) Underground Tanks. Under no circumstances whatsoever will Tenant have the right to install any underground storage tank on or about the Premises or the Project. If underground or other storage tanks storing Hazardous Materials located on the Premises or the Project before the Commencement Date are used by Tenant, Tenant shall install, use, monitor, operate, maintain, upgrade and manage such storage tanks, maintain appropriate records, obtain and maintain appropriate insurance, implement reporting procedures, properly close any underground storage tank if required by applicable Legal Requirements, and take or cause to be taken all other actions necessary or required under applicable state and federal Legal Requirements, as such now exists or may hereafter be adopted or amended in connection with the installation, use, maintenance, management, operation, upgrading and closure of such storage tanks.

(f) Control Areas. Tenant shall be allowed to utilize up to its pro rata share of the Hazardous Materials inventory within any control area or zone (located within the Premises), as designated from time to time by the applicable building code or other Legal Requirement, for Hazardous Materials use or storage. As used in the preceding sentence, Tenant’s pro rata share of any control area or zone located within the Premises shall be determined based on the rentable square footage that Tenant leases within the applicable control area or zone. For purposes of example only, if a control area or zone contains 10,000 rentable square feet and 2,000 rentable square feet of a tenant’s premises are located within such control area or zone (while such premises as a whole contains 5,000 rentable square feet), the applicable tenant’s pro rata share of such control area or zone would be 20%
(g) Tenant’s Obligations. Tenant’s obligations under this Section 30 shall survive the expiration or earlier termination of this Lease for the applicable statute of limitations period under federal, state, or local Legal Requirement. During any period of time after the expiration or earlier termination of this Lease required by Tenant or Landlord to complete the removal from the Premises of any Hazardous Materials (including, without limitation, the release and termination of any licenses or permits restricting the use of the Premises and the completion of the approved Surrender Plan), Tenant shall continue to pay the full Rent in accordance with this Lease for any portion of the Premises not relet by Landlord in Landlord’s sole discretion, which Rent shall be prorated daily.

(h) Definitions. As used herein, (i) the term “Environmental Requirements” means all applicable present and future statutes, regulations, ordinances, rules, codes, judgments, orders or other similar enactments of any Governmental Authority regulating or relating to health, safety, or environmental conditions on, under, or about the Premises or the Project, or the environment, including without limitation, the following: the Comprehensive Environmental Response, Compensation and Liability Act; the Resource Conservation and Recovery Act; and all state and local counterparts thereof, and any regulations or policies promulgated or issued thereunder, and (ii) the term “Hazardous Materials” means and includes any substance, material, waste, pollutant, or contaminant listed or defined as hazardous or toxic, or regulated by reason of its impact or potential impact on humans, animals and/or the environment under any Environmental Requirements, asbestos and petroleum, including crude oil or any fraction thereof, natural gas liquids, liquefied natural gas, or synthetic gas usable for fuel (or mixtures of natural gas and such synthetic gas). As defined in Environmental Requirements, Tenant is and shall be deemed to be the “operator” of Tenant’s “facility” and the “owner” of all Hazardous Materials brought on the Premises by Tenant or any Tenant Party, and the wastes, by-products, or residues generated, resulting, or produced therefrom.

31. Tenant’s Remedies/Limitation of Liability. Landlord shall not be in default hereunder unless Landlord fails to perform any of its obligations hereunder within 30 days after written notice from Tenant specifying such failure (unless such performance will, due to the nature of the obligation, require a period of time in excess of 30 days, then after such period of time as is reasonably necessary). Upon any default by Landlord, Tenant shall give notice by registered or certified mail to any Holder of a Mortgage covering the Premises and to any landlord of any lease of property in or on which the Premises are located and Tenant shall offer such Holder and/or landlord a reasonable opportunity to cure the default, including time to obtain possession of the Project by power of sale or a judicial action if such should prove necessary to effect a cure; provided Landlord shall have furnished to Tenant in writing the names and addresses of all such persons who are to receive such notices. All obligations of Landlord hereunder shall be construed as covenants, not conditions; and, except as may be otherwise expressly provided in this Lease, Tenant may not terminate this Lease for breach of Landlord’s obligations hereunder.

Notwithstanding the foregoing, if any claimed Landlord default hereunder will immediately, materially and adversely affect Tenant’s ability to conduct its business in the Premises or creates the reasonable likelihood of damage to persons or material damage to property or material financial loss to Tenant (a “Material Landlord Default”), and if Tenant gives Landlord written notice of such claim, Landlord shall then have 2 business days to commence cure of such claim. If Landlord fails to commence cure of such claimed Material Landlord Default and shall diligently prosecute such cure to completion. If such claimed Material Landlord Default is subsequently determined not to be a default by Landlord hereunder, Landlord shall be entitled to recover from Tenant, in Additional Rent, any costs reasonably incurred by Landlord to effect such cure. If Landlord fails to commence cure of any claimed Material Landlord Default as provided above, Tenant may commence and prosecute such cure to completion, and shall be entitled to recover the costs of such cure (but not any consequential or other damages) within 30 days after receipt of invoice to Landlord, together with interest at the Default Rate accruing upon any late payment thereof, from Landlord, to the extent of Landlord’s obligation to cure such claimed Material Landlord Default hereunder, subject to the limitations set forth in the immediately preceding sentence of this paragraph and the other provisions of this Lease.
32. Inspection and Access. Landlord and its agents, representatives, and contractors may enter the Premises at any reasonable time to inspect the Premises and to make such repairs as may be required or permitted pursuant to this Lease and for any other business purpose. Landlord and Landlord’s representatives may enter the Premises during business hours on not less than 48 hours advance written notice (except in the case of emergencies in which case no such notice shall be required and such entry may be at any time) for the purpose of effecting any such repairs, inspecting the Premises, showing the Premises to prospective purchasers and, during the last year of the Term, to prospective tenants or for any other business purpose; provided, however, that except for emergencies, Landlord shall use commercially reasonable efforts in connection with any entry not to materially interfere with Tenant’s use of the Premises. Landlord may erect a suitable sign on the Premises stating the Premises are available to let or that the Project is available for sale. Landlord may grant easements, make public dedications, designate Common Areas and create restrictions on or about the Premises; provided that no such easement, dedication, designation or restriction materially, adversely affects Tenant’s use or occupancy of the Premises or the Permitted Use. At Landlord’s request, Tenant shall execute such instruments as may be reasonably necessary for such easements, dedications or restrictions. Tenant shall at all times, except in the case of emergencies, have the right to escort Landlord or its agents, representatives, contractors or guests while the same are in the Premises, provided such escort does not materially and adversely affect Landlord’s access rights hereunder.

33. Security. Tenant acknowledges and agrees that security devices and services, if any, while intended to deter crime may not in given instances prevent theft or other criminal acts and that Landlord is not providing any security services with respect to the Premises. Tenant agrees that Landlord shall not be liable to Tenant for, and Tenant waives any claim against Landlord with respect to, any loss by theft or any other damage suffered or incurred by Tenant in connection with any unauthorized entry into the Premises or any other breach of security with respect to the Premises. Tenant shall be solely responsible for the personal safety of Tenant’s officers, employees, agents, contractors, guests and invitees while any such person is in, on or about the Premises and/or the Project. Tenant shall at Tenant’s cost obtain insurance coverage to the extent Tenant desires protection against such criminal acts.

34. Force Majeure. Neither Landlord nor Tenant shall be responsible or liable for delays in the performance of its obligations hereunder when caused by, related to, or arising out of acts of God, strikes, lockouts, or other labor disputes, embargoes, quarantines, weather, national, regional, or local disasters, calamities, or catastrophes, inability to obtain labor or materials (or reasonable substitutes therefore) at reasonable costs or failure of, or inability to obtain, utilities necessary for performance, governmental restrictions, orders, limitations, regulations, or controls, national emergencies, delay in issuance or revocation of permits, enemy or hostile governmental action, terrorism, insurrection, riots, civil disturbance or commotion, fire or other casualty, and other causes or events beyond the reasonable control of such party ("Force Majeure"); provided, however, that in no event shall Force Majeure excuse Tenant from performing any monetary obligation under this Lease.

Copyright © 2007, Alexandria Real Estate Equities, Inc.
ALL RIGHTS RESERVED. Confidential and Proprietary - Do Not Copy or Distribute. Alexandria and the Alexandria Logo are registered trademarks of Alexandria Real Estate Equities, Inc.
35. **Brokers.** Landlord and Tenant each represents and warrants that it has not dealt with any broker, agent or other person (collectively, “Broker”) in connection with this transaction and that no Broker brought about this transaction, other than CBRE and Scheer Partners, Inc. (“SPI”). CBRE shall be paid by Landlord pursuant to a separate agreement between Landlord and CBRE, and SPI shall be paid by Landlord pursuant to a separate agreement between Landlord and SPI. Landlord and Tenant each hereby agree to indemnify and hold the other harmless from and against any claims by any Broker, other than CBRE and SPI, claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this leasing transaction.

36. **Limitation on Landlord’s Liability.** Notwithstanding anything set forth herein or in any other agreement between Landlord and Tenant to the contrary: (A) Landlord shall not be liable to Tenant or any other person for (and Tenant and each such other person assume all risk of) loss, damage or injury, whether actual or consequential to: Tenant’s personal property of every kind and description, including without limitation trade fixtures, equipment, inventory, scientific research, scientific experiments, laboratory animals, product, specimens, samples, and/or scientific, business, accounting and other records of every kind and description kept at the Premises and any and all income derived or derivable therefrom; (B) there shall be no personal recourse to Landlord for any act or occurrence in, on or about the Premises or arising in any way under this Lease or any other agreement between Landlord and Tenant with respect to the subject matter hereof and any liability of Landlord hereunder shall be strictly limited solely to Landlord’s interest in the Project or any proceeds from sale or condemnation thereof and any insurance proceeds payable in respect of Landlord’s interest in the Project or in connection with any such loss; and (C) in no event shall any personal liability be asserted against any of Landlord’s officers, directors, employees, agents or contractors. Under no circumstances shall Landlord or any of Landlord’s officers, directors, employees, agents or contractors be liable for injury to Tenant’s business or for any loss of income or profit therefrom.

37. **Severability.** If any clause or provision of this Lease is illegal, invalid or unenforceable under present or future laws, then and in that event, it is the intention of the parties hereto that the remainder of this Lease shall not be affected thereby. It is also the intention of the parties to this Lease that in lieu of each clause or provision of this Lease that is illegal, invalid or unenforceable, there be added, as a part of this Lease, a clause or provision as similar in effect to such illegal, invalid or unenforceable clause or provision as shall be legal, valid and enforceable. This Lease, including the exhibits attached hereto, constitutes the entire agreement between Landlord and Tenant pertaining to the subject matter hereof and supersedes all prior agreements, understandings, letters of intent, negotiations, and discussions, whether oral or written, of the parties, and there are no warranties, representations, or other agreements, express or implied, made to either party by the other party in connection with the subject matter hereof except as specifically set forth herein or in the documents delivered pursuant hereto or in connection herewith.

38. **Signs; Exterior Appearance.** Tenant shall not, without the prior written consent of Landlord, which may be granted or withheld in Landlord’s sole discretion: (i) attach any awnings, exterior lights, decorations, balloons, flags, pennants, banners, painting or other projection to any outside wall of the Project, (ii) use any curtains, blinds, shades or screens other than Landlord’s standard window coverings, (iii) coat or otherwise sunscreen the interior or exterior of any windows, (iv) place any bottles, parcels, or other articles on the window sills, (v) place any equipment, furniture or other items of personal property on any exterior balcony, or (vi) paint, affix or exhibit on any part of the Premises or the Project any signs, notices, window or door lettering, placards, decorations, or advertising media of any type that can be viewed from the exterior of the Premises. Interior signs on doors and the directory tablet shall be inscribed, painted or affixed for Tenant by Landlord at the sole cost and expense of Tenant, and shall be of a size, color and type acceptable to Landlord. Nothing may be placed on the exterior of corridor walls or corridor doors other than Landlord’s standard lettering. The directory tablet shall be provided exclusively for the display of the name and location of tenants.
(a) Identification Signage. Landlord shall, at its expense, place Tenant’s name on the existing monument sign in front of the Building, the suite entry, and loading dock.

(b) Façade Signage. If and when Tenant leases more than 50% of the rentable square footage in the Building, Tenant shall have the exclusive right, at its sole cost and expense and in compliance with all applicable Legal Requirements, to install and affix to the façade of the Building facing Clopper Road a single sign bearing Tenant’s name and its then current corporate logo ("Identification Signage"). Such Identification Signage right shall be personal to Kite Pharma, Inc. and the transferee under any Permitted Assignment. Landlord shall have the right to approve the place, size (the area of the Identification Signage shall be equal to Tenant’s proportionate share of the Project in relation to the area of the Premises), and design of the Identification Signage, which approval shall not be unreasonably withheld, delayed, or conditioned, and shall in all cases comply with building standard signage requirements. On the expiration or earlier termination of this Lease, Tenant shall remove the Identification Signage at its sole cost and expense and in accordance with all applicable Legal Requirements.
41. Roof Equipment. As long as Tenant is not in default under this Lease, Tenant shall have the right at its sole cost and expense, subject to compliance with all Legal Requirements, to install, maintain, and remove on the top of the roof of the Building (based on Tenant’s proportionate share of the space available on the roof) directly above the Premises one or more satellite dishes, communication antennae, or other equipment (all of which having a diameter and height acceptable to Landlord) for the transmission or reception of communication of signals as Tenant may from time to time desire (collectively, the “Roof Equipment”) at no rental charge to Tenant on the following terms and conditions:

(a) Requirements. Tenant shall submit to Landlord (i) the plans and specifications for the installation of the Roof Equipment, (ii) copies of all required governmental and quasi-governmental permits, licenses, and authorizations that Tenant will and must obtain at its own expense, with the cooperation of Landlord, if necessary for the installation and operation of the Roof Equipment, and (iii) an insurance policy or certificate of insurance evidencing insurance coverage as required by this Lease and any other insurance as reasonably required by Landlord for the installation and operation of the Roof Equipment. Landlord shall not unreasonably withhold or delay its approval for the installation and operation of the Roof Equipment; provided, however, that Landlord may reasonably withhold its approval if the installation or operation of the Roof Equipment (A) may damage the structural integrity of the Building, (B) may void, terminate, or invalidate any applicable roof warranty, (C) may interfere with any service provided by Landlord or any tenant of the Building, (D) may reduce the leaseable space in the Building, or (E) is not properly screened from the viewing public.

(b) No Damage to Roof. If installation of the Roof Equipment requires Tenant to make any roof cuts or perform any other roofing work, such cuts shall only be made to the roof area of the Building located directly above the Premises and only in the manner designated in writing by Landlord; and any such installation work (including any roof cuts or other roofing work) shall be performed by Tenant, at Tenant’s sole cost and expense by a roofing contractor designated by Landlord. If Tenant or its agents shall otherwise cause any damage to the roof during the installation, operation, and removal of the Roof Equipment such damage shall be repaired promptly at Tenant’s expense and the roof shall be restored in the same condition it was in before the damage. Landlord shall not charge Tenant Additional Rent for the installation and use of the Roof Equipment. If, however, Landlord’s insurance premium or Tax assessment increases as a result of the Roof Equipment, Tenant shall pay such increase as Additional Rent within 10 days after receipt of a reasonably detailed invoice from Landlord. Tenant shall not be entitled to any abatement or reduction in the amount of Rent payable under this Lease if for any reason Tenant is unable to use the Roof Equipment. In no event whatsoever shall the installation, operation, maintenance, or removal of the Roof Equipment by Tenant or its agents void, terminate, or invalidate any applicable roof warranty.

(c) Protection. The installation, operation, and removal of the Roof Equipment shall be at Tenant’s sole risk. Tenant shall indemnify, defend, and hold Landlord harmless from and against any and all claims, costs, damages, liabilities and expenses (including, but not limited to, attorneys’ fees) of every kind and description that may arise out of or be connected in any way with Tenant’s installation, operation, or removal of the Roof Equipment.

(d) Removal. At the expiration or earlier termination of this Lease or the discontinuance of the use of the Roof Equipment by Tenant, Tenant shall, at its sole cost and expense, remove the Roof Equipment from the Building. Tenant shall leave the portion of the roof where the Roof Equipment was located in good order and repair, reasonable wear and tear excepted. If Tenant does not so remove the Roof Equipment, Tenant hereby authorizes Landlord to remove and dispose of the Roof Equipment and charge Tenant an Additional Rent for all costs and expenses incurred by Landlord in such removal and disposal. Tenant agrees that Landlord shall not be liable for any Roof Equipment or related property disposed of or removed by Landlord.
(e) **No Interference.** The Roof Equipment shall not interfere with the proper functioning of any telecommunications equipment or devices that have been installed or will be installed by Landlord or for any other tenant or future tenant of the Building. Tenant acknowledges that other tenants may have approval rights over the installation and operation of telecommunications equipment and devices on or about the roof, and that Tenant’s right to install and operate the Roof Equipment is subject and subordinate to the rights of such other tenants. Tenant agrees that any other tenant of the Building that currently has or in the future takes possession of any portion of the Building will be permitted to install such telecommunications equipment that is of a type and frequency that will not cause unreasonable interference to the Roof Equipment.

(f) **Relocation.** Landlord shall have the right, at its expense and after 60 days prior notice to Tenant, to relocate the Roof Equipment to another site on the roof of the Building as long as such site reasonably meets Tenant’s sight line and interference requirements and does not unreasonably interfere with Tenant’s use and operation of the Roof Equipment.

(g) **Access.** Landlord grants to Tenant the right of ingress and egress on a 24 hour 7 day per week basis to install, operate, and maintain the Roof Equipment. Before receiving access to the roof of the Building, Tenant shall give Landlord at least 24 hours’ advance written or oral notice, except in emergency situations, in which case 2 hours’ advance oral notice shall be given by Tenant. Landlord shall supply Tenant with the name, telephone, and pager numbers of the contact individual(s) responsible for providing access during emergencies.

(h) **Appearance.** If permissible by Legal Requirements, the Roof Equipment shall be painted the same color as the Building so as to render the Roof Equipment virtually invisible from ground level.

(i) **No Assignment.** The right of Tenant to use and operate the Roof Equipment shall be personal solely to Kite Pharma, Inc. and the transferee under any Permitted Assignment, and (i) no other person or entity shall have any right to use or operate the Roof Equipment, and (ii) Tenant shall not assign, convey, or otherwise transfer to any person or entity any right, title, or interest in all or any portion of the Roof Equipment or the use and operation thereof.

42. **Termination Option.** Notwithstanding anything to the contrary contained herein, Tenant shall have a one-time option to terminate this Lease (“Termination Option”) in accordance with the following terms and conditions:

(a) **Tenant Gives Notice.** If Tenant desires to exercise the Termination Option, Tenant shall give Landlord irrevocable written notice (“Termination Notice”) of Tenant’s exercise of the Termination Option. Landlord must receive the Termination Notice no later than the date that is 12 full months before the Termination Date. Time is of the essence with respect to Landlord’s receipt of the Termination Notice and all other deadlines in this Section.

(b) **Termination Date.** If Tenant gives the Termination Notice and complies with all the provisions in this Section, this Lease shall terminate at midnight at the end of the 84th month after the Rent Commencement Date (“Termination Date”).

(c) [***]
(d) **Tenant’s Obligation Survives Termination.** Tenant’s obligations to pay Base Rent and Additional Rent under this Lease, and to perform all other Lease obligations for the period up to and including the Termination Date, shall survive the termination of this Lease.

(e) **Landlord May Cancel and Void Termination if Tenant in Default.** Notwithstanding the foregoing provisions of this Section, if Tenant shall exercise the Termination Option (in accordance with paragraph (a) above) when it is in Default, then Landlord may elect, but is not obligated, to cancel and declare null and void Tenant’s exercise of the Termination Option and this Lease shall continue in full force and effect for the full Term unaffected by Tenant’s exercise of the Termination Option. If Landlord does not cancel Tenant’s exercise of the Termination Option after such Default, Tenant shall cure any Default within the period of time specified in this Lease and this obligation shall survive the Termination Date.

(f) **Tenant Shall Surrender Space by Termination Date.** If Tenant exercises the Termination Option, Tenant shall surrender full and complete possession of the Premises to Landlord on or before the Termination Date vacant, broom-clean, in good order and condition, and in accordance with the provisions of this Lease (including, but not limited to, Section 28), and thereafter the Premises shall be free and clear of all leases, tenancies, and rights of occupancy of any entity claiming by, through, or under Tenant.

(g) **Failure to Surrender Makes Tenant a Holdover.** If Tenant shall fail to deliver possession of the Premises on or before the Termination Date in accordance with the terms hereof, Tenant shall be deemed to be a holdover tenant from and after the Termination Date, and in such event, Tenant shall be subject to the provisions of Section 8 relating to holdover tenancies.

(h) **Lease Ceases After Termination.** If Tenant properly and timely exercises the Termination Option and properly and timely satisfies all other monetary and non-monetary obligations under this Lease, this Lease shall cease and expire on the Termination Date with the same force and effect as if the Termination Date were the date originally provided in this Lease as the expiration date of the Term.

(i) **No Termination Option After Assignment.** If this Lease has been assigned other than pursuant to a Permitted Assignment, the Termination Option shall be deemed null and void and neither Tenant nor any assignee shall have the right to exercise the Termination Option during the term of such assignment.

43. Miscellaneous.

(a) **Notices.** All notices or other communications between the parties shall be in writing and shall be deemed duly given upon delivery or refusal to accept delivery by the addressee thereof if delivered in person, or upon actual receipt if delivered by reputable overnight guaranty courier, addressed and sent to the parties at their addresses set forth above. Landlord and Tenant may from time to time by written notice to the other designate another address for receipt of future notices.

(b) **Joint and Several Liability.** If and when included within the term “Tenant,” as used in this instrument, there is more than one person or entity, each shall be jointly and severally liable for the obligations of Tenant.
(i) **Financial Information.** Tenant shall furnish Landlord with true and complete copies of (i) Tenant’s most recent audited annual financial statements within 90 days of the end of each of Tenant’s fiscal years during the Term, (ii) Tenant’s most recent unaudited quarterly financial statements within 45 days of the end of each of Tenant’s first three fiscal quarters of each fiscal year during the Term, and (iii) any other financial information or summaries that Tenant typically provides to its lenders or shareholders. The foregoing notwithstanding, so long as Tenant’s stock is listed for trading on the NASDAQ stock market or other public stock exchange and whose financial statements are publicly available within 3 months after the end of each calendar quarter, Tenant’s obligation to provide such financial statements and information shall be deemed satisfied by the availability of on-line access to U.S. Securities and Exchange Commission filings and other financial information of Kite Pharma, Inc. on its corporate website at [http://www.kitepharma.com](http://www.kitepharma.com).

(d) **Recordation.** Neither this Lease nor a memorandum of lease shall be filed by or on behalf of Tenant in any public record. Landlord may prepare and file, and upon request by Landlord Tenant will execute, a memorandum of lease.

(e) **Interpretation.** The normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of this Lease or any exhibits or amendments hereto. Words of any gender used in this Lease shall be held and construed to include any other gender, and words in the singular number shall be held to include the plural, unless the context otherwise requires. The captions inserted in this Lease are for convenience only and in no way define, limit or otherwise describe the scope or intent of this Lease, or any provision hereof, or in any way affect the interpretation of this Lease.

(f) **Not Binding Until Executed.** The submission by Landlord to Tenant of this Lease shall have no binding force or effect, shall not constitute an option for the leasing of the Premises, nor confer any right or impose any obligations upon either party until execution of this Lease by both parties.

(g) **Limitations on Interest.** It is expressly the intent of Landlord and Tenant at all times to comply with applicable law governing the maximum rate or amount of any interest payable on or in connection with this Lease. If applicable law is ever judicially interpreted so as to render usurious any interest called for under this Lease, or contracted for, charged, taken, reserved, or received with respect to this Lease, then it is Landlord’s and Tenant’s express intent that all excess amounts theretofore collected by Landlord be credited on the applicable obligation (or, if the obligation has been or would thereby be paid in full, refunded to Tenant), and the provisions of this Lease immediately shall be deemed reformed and the amounts thereafter collectible hereunder reduced, without the necessity of the execution of any new document, so as to comply with the applicable law, but so as to permit the recovery of the fullest amount otherwise called for hereunder.

(h) **Choice of Law.** Construction and interpretation of this Lease shall be governed by the internal laws of the state in which the Premises are located, excluding any principles of conflicts of laws.

(i) **Time.** Time is of the essence as to the performance of Tenant’s obligations under this Lease.

(j) **OFAC.** Tenant, and all beneficial owners of Tenant, are currently (i) in compliance with and shall at all times during the Term of this Lease remain in compliance with the regulations of the Office of Foreign Assets Control (“OFAC”) of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the “OFAC Rules”), (ii) not listed on, and shall not during the Term of this Lease be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List, or the Sectoral Sanctions Identifications List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (iii) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.
(k) Incorporation by Reference. All exhibits and addenda attached hereto are hereby incorporated into this Lease and made a part hereof. If there is any conflict between such exhibits or addenda and the terms of this Lease, such exhibits or addenda shall control.

(l) No Accord and Satisfaction. No payment by Tenant or receipt by Landlord of a lesser amount than the monthly installment of Base Rent or any Additional Rent will be other than on account of the earliest stipulated Base Rent and Additional Rent, nor will any endorsement or statement on any check or letter accompanying a check for payment of any Base Rent or Additional Rent be an accord and satisfaction. Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of such Rent or to pursue any other remedy provided in this Lease.

(m) Confidential Information. Except as expressly permitted in this Section 43(m), neither party will, without the prior written consent of the other party, disclose any Confidential Information of the other party to any third party. Information will be considered “Confidential Information” of a party if either (i) it is disclosed by the party to the other party in tangible form and is conspicuously marked “Confidential”, “Proprietary” or the like; or (ii) (A) it is disclosed by one party to the other party in non-tangible form and is identified as confidential at the time of disclosure; and (B) it contains the disclosing party’s customer lists, customer information, technical information, pricing information, pricing methodologies, or information regarding the disclosing party’s business planning or business operations; or (iii) it is disclosed to Tenant or its representatives, agents, or consultants in connection with the exercise of any audit right by Tenant under this Lease or the Work Letter, including, the audit right set forth in Section 5 of this Lease. In addition, notwithstanding anything in this Lease to the contrary, the terms of this Lease (but not its mere existence) will be deemed Confidential Information of each party. Tenant acknowledges and agrees that it will not take the position that this Lease is a material agreement for purposes of the Securities Exchange Act of 1934 or the Securities Act of 1933 or must be publicly filed with any governmental agency.

(i) Confidential Information - Exceptions. Other than the terms and conditions of this Lease, information will not be deemed Confidential Information hereunder if such information (i) is known to the receiving party prior to receipt from the disclosing party directly or indirectly from a source other than one having an obligation of confidentiality to the disclosing party; (ii) becomes known (independently of disclosure by the disclosing party) to the receiving party directly or indirectly from a source other than one having an obligation of confidentiality to the disclosing party; (iii) becomes publicly known or otherwise ceases to be secret or confidential, except through a breach of this Lease by the receiving party; or (iv) is independently developed by the receiving party. The terms and conditions of this Lease will cease being confidential if, and only to the extent that, they become publicly known, except through a breach of this Lease by the receiving party.

(ii) Confidentiality - Exceptions. Each party will secure and protect the Confidential Information of the other party (including, without limitation, the terms of this Lease) in a manner consistent with the steps taken to protect its own trade secrets and confidential information, but not less than a reasonable degree of care. Each party may disclose the other party’s Confidential Information where (i) the disclosure is required by applicable Legal Requirement or by an order of a court or other governmental body having jurisdiction after giving reasonable notice to the other party with adequate time for such other party to seek a protective order; (ii) if in the reasonable opinion of counsel for such party, disclosure is advisable under any applicable securities laws regarding public disclosure of business information; (iii) the disclosure is reasonably necessary and is to that party’s or its affiliates’ employees, officers, directors, members, attorneys, accountants, lenders, underwriters, prospective purchasers, analysts, tax preparers, bank personnel, brokers, consultants and other advisors, or the disclosure is otherwise necessary for a party to exercise its rights and perform its obligations under this Lease.
Lease, so long as in all cases the disclosure is no broader than necessary and the disclosing party instructs the receiving party to maintain the confidentiality of the Confidential Information, or (iv) the disclosure is reasonably necessary in the course of operations of the Project or business of Landlord and its affiliates, including, without limitation, capital formation.

(o) **Hazardous Activities.** Notwithstanding any other provision of this Lease, Landlord, for itself and its employees, agents and contractors, reserves the right to refuse to perform any repairs or services in any portion of the Premises that, pursuant to Tenant’s routine safety guidelines, practices or custom or prudent industry practices, require any form of protective clothing or equipment other than safety glasses. In any such case, Tenant shall contract with parties who are acceptable to Landlord, in Landlord's reasonable discretion, for all such repairs and services, and Landlord shall, to the extent required, equitably adjust Tenant’s Share of Operating Expenses in respect of such repairs or services to reflect that Landlord is not providing such repairs or services to Tenant.

(p) **Attorneys' Fees.** If any action is brought by either party against the other party, relating to or arising out of this Lease or the enforcement hereof, the prevailing party shall be entitled to recover from the other party reasonable attorneys’ fees, costs and expenses incurred in connection with the prosecution or defense of such action. For purposes of this Lease, the term “attorneys’ fees” or “attorneys’ fees and costs” shall mean the fees and expenses of counsel to the parties hereto, which may include printing, photostating, duplicating and other expenses, air freight charges, and fees billed for law clerks, paralegals and other persons not admitted to the bar but performing services under the supervision of an attorney, and the costs and fees incurred in connection with the enforcement or collection of any judgment obtained in any such proceeding. Such expenses are recoverable at all levels, including appeals and post-judgment actions or proceedings. The provisions of this Section shall survive the entry of any judgment, and shall not merge, or be deemed to have merged, into any judgment.

[ Signatures on next page ]

Copyright © 2007, Alexandria Real Estate Equities, Inc.
ALL RIGHTS RESERVED. Confidential and Proprietary — Do Not Copy or Distribute. Alexandria and the Alexandria Logo are registered trademarks of Alexandria Real Estate Equities, Inc.
IN WITNESS WHEREOF, Landlord and Tenant have executed this Lease under seal as of the day and year first above written.

TENANT:

KITE PHARMA, INC.,
a Delaware corporation

By: /s/ Tim Moore (SEAL)
NAME: Tim Moore
Title: EVP Technical Operations

TECH PARK 270 III, LLC,
a Maryland limited liability company

By: ARE-MM Tech Park 270 III, LLC,
a Delaware limited liability company, managing member

By: ARE-930 Clopper Road, LLC,
a Delaware limited liability company, managing member

By: Alexandria Real Estate Equities, L.P.,
a Delaware limited partnership, managing member

By: ARE-QRS CORP.,
a Maryland corporation, general partner

By: /s/ Eric S. Johnson (SEAL)
NAME: Eric S. Johnson
Title: Senior Vice President
RE Legal Affairs

Copyright © 2007, Alexandria Real Estate Equities, Inc.
ALL RIGHTS RESERVED. Confidential and Proprietary - Do Not Copy or Distribute. Alexandria and the Alexandria Logo are registered trademarks of Alexandria Real Estate Equities, Inc.
EXHIBIT B TO LEASE
DESCRIPTION OF PROJECT

[***]

[***]

[***]

[***]

[***]

Copyright © 2007, Alexandria Real Estate Equities, Inc.
ALL RIGHTS RESERVED. Confidential and Proprietary - Do Not Copy or Distribute. Alexandria and the Alexandria Logo are registered trademarks of Alexandria Real Estate Equities, Inc.
EXHIBIT C-2 TO LEASE
WORK LETTER

[***]
[***]
[***]

1. [***]
   (a) [***]
   (b) [***]
   (c) [***]

2. [***]
   (a) [***]
   (b) [***]
(b) [***]
(c) [***]
(d) [***]

4. [***]
(a) [***]
(b) [***]

5. [***]
(a) [***]
6. [***]
   (a) [***]
   (b) [***]
A articles [***]

(*** registered trademarks of Alexandria Real Estate Equities, Inc.)
THIRD AMENDMENT TO LEASE AGREEMENT

THIS THIRD AMENDMENT TO LEASE AGREEMENT ("this Third Amendment") is made as of this 24 day of September, 2018 ("Effective Date"), between TECH PARK 270 III, LLC, a Maryland limited liability company, having an address at 385 E. Colorado Boulevard, Suite 299, Pasadena, California 91101 ("Landlord"), and KITE PHARMA, INC., a Delaware corporation, having an address at Suite 200, 930 Clopper Road, Gaithersburg, Maryland 20878-1301 ("Tenant").

RECITALS

A. Landlord and Tenant have entered into that certain Lease Agreement ("Original Lease") dated as of December 1, 2017, as amended by that certain First Amendment to Lease Agreement dated January 29, 2018 ("First Amendment"), and that certain Second Amendment to Lease Agreement dated February 26, 2018 ("Second Amendment"; together with the Original Lease and the First Amendment, the "Lease"), wherein Landlord leased to Tenant approximately [***] rentable square feet ("Existing Premises") located at Suite 200, 930 Clopper Road, Gaithersburg, Maryland 20878-1301, as more particularly described in the Lease,

B. Landlord and Tenant desire to amend the Lease, among other things, to expand the Existing Premises by an additional 33,919 rentable square feet ("Expansion Premises") so that Tenant will lease the entire Building, to provide a tenant improvement allowance to Tenant, and to modify certain of Landlord and Tenant’s maintenance and repair obligations.

AGREEMENT

Now, therefore, the parties hereto agree that, as of the Effective Date, the Lease is amended as follows:

1. Definitions. Terms used in this Third Amendment but not otherwise defined shall have the meanings set forth in the Lease.

2. Expansion Premises. Effective as of the Expansion Premises Commencement Date (as defined below), (a) the Existing Premises shall be expanded to include the Expansion Premises, and (b) Exhibit A to this Third Amendment, which depicts the Expansion Premises as the hatched area, is hereby added to Exhibit A to the Lease.

3. Changes to Defined Terms. Effective as of the Expansion Premises Commencement Date, the following amendments are hereby made to the definitions contained on page 1 of the Lease in the Basic Lease Provisions:

   a. The defined term "Premises" shall be deleted in its entirety and replaced with the following:

   "Premises: That portion of the Project, containing approximately 60,022 rentable square feet, as determined by Landlord, consisting of (a) approximately 26,103 rentable square feet of space shown as the hatched area on Exhibit A to this Lease ("Existing Premises"), and (b) approximately 33,919 rentable square feet of space shown on Exhibit A to this Lease and identified therein as the "Expansion Premises" ("Expansion Premises"). Gaudreau, Inc., Landlord's architect, has measured the area of the Premises pursuant to the 1996 Standard Method of Measuring Floor Area in Office Buildings as adopted by the Building Owners and Managers Association (ANSI/BOMA 265.1-1996) ("BOMA Standards"). Tenant acknowledges receipt of such measurement, and Landlord and Tenant each confirm that such measurement shall be conclusive as to the area of the Premises.

Copyright © 2012. Alexandria Real Estate Equities, Inc. ALL RIGHTS RESERVED. Confidential and Proprietary. Do Not Copy or Distribute. Alexandria and Alexandria Logo are registered trademarks of Alexandria Real Estate Equities, Inc.
b. The defined term “Rentable Area of the Premises” shall mean approximately 60,022 rentable square feet.

c. The defined term “Tenant’s Share of Operating Expenses” shall mean 100%.

4. Delivery of Expansion Premises. On the Effective Date and as long as Tenant has delivered to landlord the evidence of insurance required by the Lease with respect to the entire Premises, Tenant shall have full access to the Expansion Premises. The commencement date for the Expansion Premises shall be October 1, 2018 (“Expansion Premises Commencement Date”).

a. Except as set forth in this Third Amendment, if applicable: (i) Tenant shall accept the Expansion Premises in their broom-clean “as is” condition as of the Expansion Premises Commencement Date, which condition shall be substantially similar in all material respects to the condition of the Expansion Premises as of the Effective Date, but Landlord shall be responsible for any costs to bring the Expansion Premises into compliance with applicable Legal Requirements as of the Expansion Premises Commencement Date; as long as Tenant notifies Landlord in writing of such items that are not in compliance by no later than 6 months after the Expansion Premises Commencement Date (i.e., by no later than April 1, 2019); (ii) Landlord shall have no obligation for any defects in the Expansion Premises; and (iii) Tenant’s taking possession of the Expansion Premises shall be conclusive evidence that Tenant accepts the Expansion Premises and that the Expansion Premises were in good condition at the time possession was taken.

b. Neither Landlord nor any of its agents has made any representation or warranty with respect to the condition of all or any portion of the Expansion Premises, and/or the suitability of the Expansion Premises for the conduct of Tenant’s business, and Tenant waives any implied warranty that the Expansion Premises are suitable for the Permitted Use. Tenant shall use the Expansion Premises only for the Permitted Use under the Lease in compliance with the provisions of Section 7 of the Lease.

c. Except as set forth in this Third Amendment, Landlord shall have no obligation to perform any work at the Building in connection with Tenant’s occupancy of the Expansion Premises or obtain any permits, approvals, or entitlements related to Tenant’s specific use of the Expansion Premises or Tenant’s business operations therein.

d. Notwithstanding the foregoing provisions of this Section 4, Tenant shall have a period of 6 months after the Expansion Premises Commencement Date (i.e., by no later than April 1, 2019) to reasonably identify in writing any (i) latent defects in the mechanical, electrical, and plumbing systems and the structural components serving the Expansion Premises, and (ii) HVAC system or component that is not in good working order. For purposes of this paragraph, “latent defects” means those material defects in such systems or components that could not have been identified or discovered through a reasonable inspection of such systems or components conducted by a qualified technician. Landlord will promptly repair such identified latent defects or HVAC system or component at Landlord’s cost (and not as part of Operating Expenses), subject to Landlord’s confirmation that such defects are, in fact, latent defects or that the HVAC system or component is not, in fact, in good working order.

e. Tenant acknowledges receipt of the Focused Tenant Exit Audit dated as of March 16, 2017 relating to the prior tenant’s operations at the Expansion Premises. By no later than the Expansion Premises Commencement Date, Tenant shall have the right, at its expense, to engage a qualified environmental engineering firm to inspect the Expansion Premises before the Expansion Premises Commencement Date to determine whether, as of the date of such Landlord and Tenant each confirm that such measurement shall be conclusive as to the area of the Premises.
inspection, the Premises is in violation of any applicable Environmental Requirements. If such report indicates any such violation, Tenant shall provide a copy to Landlord and Landlord shall, at its expense (and not as an Operating Expense), take such action as is necessary to correct such violation. Tenant shall provide such access to Landlord and its agents as may be necessary to allow Landlord to correct such violation.

f. Landlord shall be responsible for the compliance of the Expansion Premises with the ADA as of the Expansion Premises Commencement Date. Thereafter, Tenant shall be responsible for the compliance of the Expansion Premises with the ADA.

g. Tenant acknowledges receipt of the letter dated August 23, 2018 addressed to Tenant from Jennerik Engineering, Inc. stating that the HVAC equipment serving the Expansion Premises is in good working order.

5. Base Rent for Expansion Premises. Tenant shall continue to pay Base Rent with respect to the Existing Premises at the rates set forth in the Lease. The Base Rent for the Expansion Premises shall be phased in as follows:

a. Commencing on the Expansion Premises Commencement Date through September 30, 2019, Base Rent for the Expansion Premises shall be payable at the rate of $40,249.58 per month (i.e., $29/rentable square foot (“rsf”) per annum x 16,655 rsf).

b. Commencing on October 1, 2019 (i.e., the first anniversary of the Expansion Premises Commencement Date), Base Rent for the Expansion Premises shall be payable at the rate of $84,430.04 per month (i.e., $29.87/rsf per annum x 33,919 rsf). The Base Rent for this period reflects the first annual increase in the Base Rent for the Expansion Premises based on the Rent Adjustment Percentage as set forth in the Basic Lease Provisions. On each anniversary of the Expansion Premises Commencement Date occurring after October 1, 2019 (i.e., October 1, 2020 and each October 1 thereafter), the Base Rent for the Expansion Premises shall be increased by multiplying the Base Rent payable for the Expansion Premises immediately before such date by the Rent Adjustment Percentage (i.e., 3%) and adding the resulting amount to the Base Rent payable for the Expansion Premises immediately before such date. Base Rent for the Expansion Premises, as so adjusted, shall thereafter be due as provided in the Lease.

6. Tenant’s Share of Operating Expenses. Tenant shall continue to pay Tenant’s Share of Operating Expenses with respect to the Existing Premises as set forth in the Lease. Commencing on the Expansion Premises Commencement Date and during the balance of the Term, Tenant’s Share of Operating Expenses for the Expansion Premises shall be 56.5% based on 33,919 rsf. As a result, commencing on the Expansion Premises Commencement Date and during the balance of the Term, Tenant’s Share of Operating Expenses for the Premises shall be 100%.

7. Electrical Submeter Installation. By no later than the Expansion Premises Commencement Date, Landlord shall, at its sole cost, install separate electrical submeters in the Expansion Premises.

8. Identification Signage. Section 38(b) of the Lease provides that if and when Tenant leases more than 50% of the rentable square footage in the Building, Tenant shall have the exclusive right, at its sole cost and expense and in compliance with all applicable Legal Requirements, to install and affix to the Identification Signage to the facade of the Building facing Clopper Road. Pursuant to Section 38(b) of the Lease, from and after the Expansion Premises Commencement Date, Tenant shall have the right to install and affix the Identification Signage as provided in Section 38(b) of the Lease.
9. Expansion Premises TI Allowance. Landlord shall provide to Tenant an additional tenant improvement allowance in an amount equal to $30 per rentable square foot of the Expansion Premises (i.e., $1,017,570) (“Expansion Premises TI Allowance”) to be used by Tenant as set forth in this Section. Other than funding the Expansion Premises TI Allowance, Landlord shall have no other obligation whatsoever with respect to making any leasehold or other improvements to the Expansion Premises. Landlord’s obligations with respect to the Expansion Premises TI Allowance shall cease upon disbursement in full of the Expansion Premises TI Allowance to or on behalf of Tenant. The Expansion Premises TI Allowance shall be used to reimburse Tenant only for the design, permits, and construction (including, without limitation, construction management and engineering fees) of modifications or improvements to the Premises (including, without limitation, modifications or improvements to the Tenant Improvements under the Original Lease) of a fixed and permanent nature desired by Tenant to the Premises (“Third Amendment Improvements”), but shall not be used to purchase any personal property or other non-Building Systems materials or equipment. Notwithstanding anything to the contrary, Landlord shall be solely responsible for, and the Expansion Premises TI Allowance shall not be reduced by, costs incurred to remove Hazardous Materials from the Expansion Premises that existed before the Expansion Premises Commencement Date or, except to the extent required as a result of the specialized nature of Tenant’s improvements, costs to bring the Expansion Premises into compliance with Legal Requirements.

a. Third Amendment Improvements; insurance. Title to the Third Amendment Improvements shall remain in the sole name of Landlord and shall not be subject to any liens or encumbrances. Landlord’s approval of the Third Amendment Improvements and Tenant’s contractors and architect for the Third Amendment Improvements shall not be unreasonably withheld, delayed, or conditioned. Tenant shall have no right to the use or benefit (including any reduction to Base Rent) of any portion of the Expansion Premises TI Allowance not required for the Third Amendment Improvements (as approved by Landlord pursuant to this Section). Before the commencement of the Third Amendment Improvements, Tenant shall deliver to Landlord a copy of any contract with Tenant’s contractors (including any architect), and certificates of insurance from any contractor performing any part of the Third Amendment Improvements evidencing industry standard commercial general liability, automotive liability, “builder’s risk”, and workers’ compensation insurance. Tenant shall cause the general contractor, if any, to provide a certificate of insurance naming Landlord, Alexandria Real Estate Equities, Inc., and Landlord’s lender (if any) as additional insureds for the general contractor’s liability coverages required above.

b. Reimbursement. Upon submission by Tenant to Landlord of a draw request in Landlord’s standard form, containing such certifications, lien waivers (including a conditional lien release for each progress payment and unconditional lien releases for the prior month’s progress payments), inspection reports, and other matters as Landlord customarily obtains for the expenses incurred by Tenant with respect to the Third Amendment Improvements, Landlord shall promptly reimburse Tenant for such expenses from the Expansion Premises TI Allowance, but only to the extent of the Expansion Premises TI Allowance. Landlord shall make the Expansion Premises TI Allowance available to Tenant for any expenses incurred for the Third Amendment Improvements made for a period of [***] after the Expansion Premises Commencement Date, i.e., such period shall end on [***] subject to extension for Force Majeure Delays to a maximum of [***] in the aggregate. Tenant shall not make more than one such submission each month to Landlord.

10. Amendment to Basic Lease Provisions (Tenant’s Notice Address). Tenant’s Notice Address under the Lease is hereby changed to the following:

Tenant’s Notice Address
Kite Pharma, Inc.
930 Clopper Road
Gaithersburg, MD 20878-1301
Attention: Head of Facilities
11. **Amendment to Section 1 (Lease of Premises).** Effective as of the Expansion Premises Commencement Date, Tenant shall lease the entire Premises and, as a result, there shall be no Common Areas as of that date. Accordingly, Section 1 of the Lease is hereby amended by adding the following sentence at the end thereof: “Notwithstanding any contrary provision contained in this Lease, as of the Expansion Premises Commencement Date there shall be no Common Areas.”

12. **Amendment to Section 7 (Use).** Effective as of the Expansion Premises Commencement Date, Section 7 of the lease is hereby amended as follows: (i) delete the 7th sentence stating “Tenant shall cause any equipment or machinery to be installed in the Premises so as to reasonably prevent sounds or vibrations from the Premises from extending into Common Areas, or other space in the Project[.]”, and (ii) delete the 8th sentence and replace it with the following new sentence stating “Tenant shall not place any machinery or equipment weighing 500 pounds or more in or upon the Premises.”

13. **Amendment to Section 7(a) (Modifications to Common Areas).** Effective as of the Expansion Premises Commencement Date, Section 7(a) of the lease is hereby amended as follows: (i) delete the first sentence in its entirety and replace it with the following: “Landlord shall be responsible for the compliance of the Building exterior and all areas of the Project outside of the Building with the ADA and other Legal Requirements as of the Commencement Date (and shall not include such costs in Operating Expenses)[.]”, and (ii) delete the phrase “Common Areas or the exterior of the Building” in the 2nd sentence and replace the same with “the Building exterior and all areas of the Project outside of the Building”.

14. **Amendment to Section 10 (Parking).** Effective as of the Expansion Premises Commencement Date, Section 10 of the Lease shall be deleted and replaced with the following new Section 10:

```
10. Parking. Subject to all legal Requirements, Force Majeure, a Taking (as defined in Section 19 below) and the exercise by Landlord of its rights hereunder, Tenant shall have the exclusive right to park in those areas of the Project designated for parking, subject to landlord’s reasonable rules and regulations at no cost to Tenant. Landlord shall not be responsible for enforcing Tenant’s parking rights against any third parties. As of the Commencement Date, the current parking ratio is 3.3 standard sized spaces per 1,000 leased rentable square feet.
```

15. **Amendment to Section 11(a) (General).** Effective as of the Expansion Premises Commencement Date, Section 11(a) of the Lease is hereby amended as follows: (i) delete the phrase “janitorial services to the Common Areas,” and (ii) delete the penultimate sentence stating “Tenant agrees to limit use of water and sewer with respect to Common Areas to normal restroom use.”
16. Amendment to Section 11. New Section 11 (d) (Generator). Effective as of the Expansion Premises Commencement Date, Section 11 of the Lease is hereby amended by adding the following new Section 11 (d):

(d) **Generator.** An emergency electricity generator ("Generator") and fuel supply system ("Fuel System"); together with the Generator, the "Generator Equipment" serve the Building as of the Commencement Date. From and after the Expansion Premises Commencement Date, Tenant shall, at its sole cost and expense, properly maintain and repair the Generator Equipment. At the expiration or earlier termination of the Term, the Generator Equipment shall remain at the Project and Tenant shall return the Generator Equipment to Landlord in the condition it was in on the Expansion Premises Commencement Date, ordinary wear and tear excepted. Tenant shall pay all governmental fees, charges, and taxes and all hook-up and disconnection fees associated with Tenant’s use of the Generator Equipment and Landlord shall have no liability therefor. All of the provisions of this Lease, including, without limitation, the insurance, maintenance, repair, and indemnification provisions set forth in this Lease shall apply and be applicable to Tenant’s operation, maintenance, replacement, and removal of the Generator Equipment. Without limiting any other obligations of Tenant set forth in this Lease, Tenant shall, at its sole cost and expense, maintain and repair the Generator Equipment and keep it in good order and operating condition.

(i) **Insurance.** If the presence of the Generator Equipment is the sole cause of an increase in Landlord’s property or liability insurance premiums for the Building, Landlord shall so inform Tenant in writing and Tenant shall pay to Landlord as Additional Rent within 10 days after demand therefor an amount equal to such increase.

(ii) **Compliance.** Tenant shall, at its sole cost and expense, comply with all Legal Requirements that may now or hereafter be applicable to the area in which the Generator Equipment is located or to the use, operation, repair, maintenance, and replacement of the Generator Equipment. The Legal Requirements include, but are not limited to, Legal Requirements (A) requiring that Tenant obtain the necessary permits and approvals for the use, operation, repair, maintenance, and replacement of the Generator Equipment, (B) prohibiting any form of pollution, (C) requiring the person discharging or permitting the discharging of Hazardous Materials or participating in the discharge or spilling of Hazardous Materials to report such discharge or spill to the proper Governmental Authorities, (D) requiring certain inspections, gauging, and recordkeeping. Tenant shall pay all costs, expenses, claims, fines, penalties, and damages that may in any manner arise out of or be imposed because of the failure of Tenant to comply with this Section. Tenant shall indemnify, defend, and hold harmless Landlord and its officers, members, directors, employees, managers, employees, agents, and contractors from all claims, injuries, damages, costs, expenses, losses, and liabilities (including, but not limited to, attorneys’ fees) arising from Tenant’s failure to comply with this Section. Each party shall promptly give notice to the other of any notice of violation received by each party.

17. Amendment to Sections 13 (Landlord’s Repairs) and 14 (Tenant’s Repairs). Effective as of the Expansion Premises Commencement Date, Sections 13 and 14 of the Lease are hereby deleted in their entirety and replaced with the following new Sections 13 and 14:

*Copyright © 2012. Alexandria Real Estate Equities, Inc. ALL RIGHTS RESERVED. Confidential and Proprietary. Do Not Copy or Distribute. Alexandria and Alexandria Logo are registered trademarks of Alexandria Real Estate Equities, Inc.*
13. **Landlord’s Repairs.** Landlord, as an Operating Expense, shall maintain the following in good repair, reasonable wear and tear and uninsured losses and damages caused by Tenant, or by any of Tenant’s agents, servants, employees, invitees and contractors (collectively, “Tenant Parties”) excluded: (a) all of the exterior structural portions of the Building, (b) roof, roof membrane, and roofing and covering materials (including performing roof surveys), (c) foundations, (d) exterior demising walls and Building façade, (e) all landscaping, sidewalks, and parking areas contained in or about the Project, including all areas covered by asphalt and concrete; (f) exterior lighting (including parking lot lighting), (g) exterior signage at the Project (excluding, however, the Identification Signage), (h) patio and patio furniture, and (i) elevators. Landlord, as an Operating Expense, shall perform snow removal, exterior washing of windows, and exterior window repair. Losses and damages caused by Tenant or any Tenant Party shall be repaired by Landlord, to the extent not covered by insurance, at Tenant’s sole cost and expense, subject to the terms of **Section 17** below regarding each party’s waiver of subrogation. Landlord reserves the right to stop the elevators and Building Systems services when necessary (i) by reason of accident or emergency, or (ii) for planned repairs, alterations or improvements, which are, in the judgment of Landlord, desirable or necessary to be made, until said repairs, alterations or improvements shall have been completed. Landlord shall have no responsibility or liability for failure to supply elevator and Building Systems services during any such period of interruption; provided, however, that Landlord shall, except in case of emergency, make a commercially reasonable effort to give Tenant 48 hours advance notice of any planned stoppage of elevator and Building Systems services for routine maintenance, repairs, alterations or improvements. Tenant shall promptly give Landlord written notice of any repair required by Landlord pursuant to this Section, after which Landlord shall have a reasonable opportunity to effect such repair. Landlord shall not be liable for any failure to make any repairs or to perform any maintenance unless such failure shall persist for an unreasonable time after Tenant’s written notice of the need for such repairs or maintenance. Tenant waives its rights under any Legal Requirement to terminate this Lease or to make such repairs at Landlord’s expense and agrees that the parties’ respective rights with respect to such matters shall be solely as set forth herein. Repairs required as the result of fire, earthquake, flood, vandalism, war, or similar cause of damage or destruction shall be controlled by **Section 18**.

14. **Tenant’s Repairs.** Except as expressly provided in **Section 13** above or in this Section, Tenant, at its expense, shall repair, replace and maintain in good condition all portions and components of the interior of the Premises, including, without limitation, (i) entries, (ii) doors, (iii) ceilings (including structural portions of the floor/ceiling slabs), (iv) interior windows, (v) interior walls, (vi) the interior side of demising walls, (vii) HVAC, mechanical, electrical, life safety, plumbing, pipes and conduits, fire sprinklers, and all other building systems serving the Premises and other portions of the Project (“Building Systems”), (viii) shafts (including elevator shafts), (ix) columns and beams, (x) emergency electrical generator (“Generator”) and related fuel supply system and infrastructure, and (xi) security cameras and related hardware installed by Landlord and used by Tenant (Tenant shall have the right to request Landlord to disconnect (but not remove) the Landlord-installed security cameras and related hardware serving the Building, which work Landlord shall promptly perform at its expense; if disconnected, such cameras and related hardware shall remain in place and maintained in such state by Tenant). Such repair and replacement may include capital expenditures and repairs whose benefit may extend beyond the Term; provided, however, that the cost to replace any HVAC system shall be allocated as set forth in **Section 16** below. Should Tenant fail to make any such repair or replacement or fail to maintain the Premises, Landlord shall give Tenant notice of such failure. If Tenant fails to commence cure of such failure within 10 days of Landlord’s notice, and thereafter diligently prosecute such cure to completion, Landlord may perform such work and shall be reimbursed the actual, reasonable cost thereof by Tenant within 10 days after demand therefor; provided, however, that if such failure by Tenant creates or could create an emergency, Landlord may immediately commence cure of such failure and shall thereafter be entitled to recover the actual, reasonable costs of such cure from Tenant. Tenant shall bear the full uninsured cost of any repair or replacement to any part of the Project that results from damage caused by Tenant or any Tenant Party and any repairs that benefit only the Premises.

*Copyright © 2012. Alexandria Real Estate Equities, Inc.*

ALL RIGHTS RESERVED. Confidential and Proprietary. Do Not Copy or Distribute. Alexandria and Alexandria Equities, Inc. Logo are registered trademarks of Alexandria Real Estate Equities, Inc.
(a) Maintenance Contracts. Tenant, at its expense, shall at all times during the Term maintain with qualified contractors maintenance and repair contracts (“Maintenance Contracts”) for all Building Systems and the Generator. The Maintenance Contracts shall be in form and content reasonably satisfactory to Landlord. Landlord shall be a third party beneficiary of the Maintenance Contracts and, within 30 days after Landlord’s request, Tenant shall deliver a copy of the Maintenance Contracts to Landlord.

(b) [***]

(c) [***]

(d) Performance Audits. Landlord shall have the ongoing right to inspect, perform maintenance audits (not to exceed twice per calendar year), and contract for an independent facility condition assessment (not to exceed once every 3 calendar years) to monitor Tenant’s maintenance and repair obligations under this Lease, the reasonable costs of which may be included in Operating Expenses. Landlord shall have the right to review Tenant’s certification records or maintenance records upon Landlord’s written request (but not to exceed once per calendar year). All repairs made by Tenant shall be at least equal in quality to the original work, and shall be made only by a licensed, bonded (if required by Landlord in its sole discretion) contractor approved in advance by Landlord, which approval shall not be unreasonably withheld, delayed, or conditioned.
(e) **Lab Systems.** Tenant acknowledges that (i) the Expansion Premises contains an autoclave, glass washer, ice maker, RO water system, compressed air system, and vacuum system (collectively, "Lab Systems"), (ii) Tenant will not use the Lab Systems during the Term, and (iii) the Lab Systems shall remain in their current location within the Expansion Premises during the Term and shall not be removed from the Expansion Premises or relocated within the Expansion Premises. By no later than the Expansion Premises commencement date, Landlord shall take such action as it deems necessary to secure the Lab Systems. From and after the Expansion Premises commencement date, Tenant shall have no obligation to maintain service contracts on the Lab Systems, but shall be responsible for repairing or replacing any Lab Systems damaged by Tenant or any Tenant Party. On the expiration or earlier termination of the Term, Tenant shall surrender the Lab Systems to Landlord in their then-current condition, ordinary wear and tear and damage by Tenant or any Tenant Party excluded.

18. **Amendment to Sections 16(b) and 30(i) (Pre-Existing Environmental Conditions).** Sections 16(b) and 30(i) of the Lease shall remain in full force and effect, but as to the Expansion Premises, Pre-Existing Environmental Conditions shall mean the presence of Hazardous Materials in, on, under, or about the Expansion Premises before the Expansion Premises commencement date.

19. **Amendment to Sections 21(c) and (d) (Default Remedies).** Sections 21(c) and 21(d) of the Lease are hereby amended by inserting "Upon a Default by Tenant hereunder," at the beginning of the first sentence thereof.

20. **Amendment to Section 21(e) (Suspension of Funding/Performance).** Section 21(e) of the Lease is hereby amended by deleting that provision in its entirety and replacing it with the following new Section 21(e):

   (e) **Suspension of Funding/Performance.** Upon a Default by Tenant hereunder and during the continuance thereof, Landlord shall have the right to suspend funding of any TI Allowance, the Expansion Premises TI Allowance, or the performance of Landlord's Work (and such suspension shall constitute a Tenant Delay [as defined in Exhibit C-1 attached hereto]).

21. **Amendment to Section 27 (Subordination).** The reference to the "Commencement Date" in the first sentence of Section 27 of the Lease shall be deemed a reference to the "Commencement Date and the Expansion Premises Commencement Date."

22. **Amendment to Section 39 (Right of First Offer).** Effective as of the Expansion Premises commencement date, Section 39 of the Lease is hereby deleted in its entirety and replaced with the words "Reserved."

23. [***]

24. [***]

   (c) [***]
25. [***]

26. Tenant’s Property. Notwithstanding anything to the contrary in the Lease, all alterations and improvements that may be installed or placed in or about the Premises, including, without limitation, the Tenant Improvements and the Third Amendment Improvements, to the extent paid for by Tenant, shall be Tenant’s property during the Term of the Lease. As such, prior to the expiration or earlier termination of the Lease, Tenant shall be entitled to all depreciation, amortization, and other tax benefits with respect thereto. All such alterations and improvements shall be and become the property of Landlord upon the expiration or earlier termination of the Lease, except to the extent Tenant is required to remove the same pursuant to the terms of the Lease.

27. No Liens. Landlord hereby waives each and every lien for rent or right of distress, whether statutory, common law, contractual, or otherwise, with respect to Tenant’s personal property in the Premises.

28. Miscellaneous.
   a. This Third Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This Third Amendment may be amended only by an agreement in writing, signed by the parties hereto.
   b. This Third Amendment is binding upon and shall inure to the benefit of the parties hereto, their respective agents, employees, representatives, officers, directors, divisions, subsidiaries, affiliates, assigns, heirs, successors in interest and shareholders.
   c. This Third Amendment may be executed in 2 or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the U.S. federal E-SIGN Act of 2000), or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Third Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.
   d. Tenant represents and warrants to Landlord that Tenant has not dealt with any broker, agent, or other person (collectively, “Broker”) in connection with this Third Amendment and that no Broker brought about this transaction, other than CBRE, Inc. (“CBRE”) and Scheer Partners, Inc. (“SPI”). CBRE, acting as Tenant’s broker, shall be paid by Landlord pursuant to a separate agreement between Landlord and CBRE. SPI, acting as Landlord’s broker, shall be paid by Landlord pursuant to a separate agreement between Landlord and SPI. Tenant hereby agrees to indemnify and hold Landlord harmless from and against any claims by any Broker (other than CBRE and SPI) claiming a commission or other form of compensation by virtue of having dealt with Tenant with regard to this Third Amendment.
   e. Except as amended and/or modified by this Third Amendment, the Lease is

Copyright © 2012. Alexandria Real Estate Equities, Inc. ALL RIGHTS RESERVED. Confidential and Proprietary. Do Not Copy or Distribute. Alexandria and Alexandria Logo are registered trademarks of Alexandria Real Estate Equities, Inc.
hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this Third Amendment. In the event of any conflict between the provisions of this Third Amendment and the provisions of the Lease, the provisions of this Third Amendment shall prevail. Regardless of whether specifically amended by this Third Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Third Amendment.

[SIGNATURES APPEAR ON NEXT PAGE]
IN WITNESS WHEREOF, the parties hereto have executed this Third Amendment under seal as of the day and year first above written.

TENANT:
KITE PHARMA, INC.,
a Delaware corporation

[Signature]
Name:
Title:

LANDLORD:
TECH PARK 270 III, LLC,
a Maryland limited liability company
By: ARE-MM Tech Park 270 III, LLC,
a Delaware limited liability company,
managing member
By: ARE-930 Clopper Road, LLC,
a Delaware limited liability company,
managing member
By: Alexandria Real Estate Equities, LP,
a Delaware limited partnership,
managing member
By:
Name:
Title:

Copyright © 2012. Alexandria Real Estate Equities, Inc.
ALL RIGHTS RESERVED. Confidential and Proprietary.
Do Not Copy or Distribute. Alexandria and Alexandria
Logo are registered trademarks of Alexandria Real Estate
Equities, Inc.
EXHIBIT A
EXPANSION PREMISES

Expansion Premises

[***]

Copyright © 2012. Alexandria Real Estate Equities, Inc.
ALL RIGHTS RESERVED. Confidential and Proprietary.
Do Not Copy or Distribute. Alexandria and Alexandria
Logos are registered trademarks of Alexandria Real Estate
Equities, Inc.
FOURTH AMENDMENT TO LEASE AGREEMENT

THIS FOURTH AMENDMENT TO LEASE AGREEMENT ("this Fourth Amendment") is made as of this Z3 day of May, 2019 ("Effective Date"), between TECH PARK 270 III, LLC, a Maryland limited liability company, having an address at 385 E. Colorado Boulevard, Suite 299, Pasadena, California 91101 ("Landlord"), and KITE PHARMA, INC., a Delaware corporation, having an address at Suite 200, 930 Clapper Road, Gaithersburg, Maryland 20878-1301 ("Tenant").

RECITALS

A. Landlord and Tenant have entered into that certain Lease Agreement ("Original Lease") dated as of December 1, 2017, as amended by that certain First Amendment to Lease Agreement dated January 29, 2018 ("First Amendment"), that certain Second Amendment to Lease Agreement dated February 26, 2018 ("Second Amendment"), and that certain Third Amendment to Lease Agreement dated September 24, 2018 ("Third Amendment"); together with the Original Lease, the First Amendment, and the Second Amendment, the "Lease"), wherein Landlord leased to Tenant approximately [***] rentable square feet ("Premises") located at Suite 200, 930 Clapper Road, Gaithersburg, Maryland 20878-1301, as more particularly described in the Lease.

B. Landlord and Tenant desire to amend the Lease, among other things, to modify the provisions governing the costs to replace certain HVAC systems serving the Premises and to allow for the removal from the Premises of certain Lab Systems.

AGREEMENT

Now, therefore, the parties hereto agree that, as of the Effective Date, the Lease is amended as follows:

1. Amendments to Certain Provisions of Section 14 (Tenant's Repairs). Effective as of the Effective Date, Sections 14(b) (HVAC System Condition), 14(c) (HVAC System Replacement), and 14(e) (Lab Systems) of the Lease are hereby deleted in their entirety and replaced with the following new Sections 14(b) (HVAC System Condition), 14(c) (Replacement of Certain Existing HVAC/Water Equipment), 14(e) (Lab Systems), and a new Section 14(f) (Boiler):

   (b) HVAC System Condition. Tenant confirms that (i) Landlord previously obtained and provided to Tenant a copy of a report prepared by Jennerik Engineering, Inc. dated August 23, 2018 and addressed to Tenant evaluating the condition of the base building HVAC system serving the Premises, and (ii) Landlord has, at its sole cost and expense, replaced the HVAC unit known as RTU-14 (Carrier Model 48GX-024040301; serial number 2501G1152) with a new HVAC unit ("Replaced HVAC Unit"). Subject to the provisions of Section 14(c) below, Tenant shall thereafter maintain, repair, and replace the Replaced HVAC Unit, the Existing HVAC/Water Equipment (as defined below), and the New HVAC/Water Equipment (as defined below) as provided in this Section 14.

   (c) Replacement of Certain Existing HVAC/Water Equipment. Notwithstanding any contrary provision contained in Section 5 (Operating Expense Payment) or Section 13 (Landlord’s Repairs) or this Section 14, the cost to replace certain of the existing HVAC units, exhaust fans, air handling units, boilers, and water pumps serving the Premises shall be governed by the provisions of this Section. For purposes of this Lease, "Existing HVAC/Water Equipment" means the following HVAC units, exhaust fans, air handling units, boilers, and water pumps serving the Premises:
(iii) **Other HVAC Systems.** Landlord shall, as an Operating Expense, promptly replace when operationally required any HVAC system that is not a Replaced HVAC Unit, an item of the Existing HVAC/Water Equipment, or an item of the New HVAC/Water Equipment ("Other HVAC Systems") with a new HVAC system of comparable tonnage. The cost of the Other HVAC System shall be amortized over the useful life of the Other HVAC System.

*e* * * * * * * * * * *

(e) **Lab Systems.** Tenant acknowledges that (i) room 330 in the Expansion Premises contains 2 autoclaves, glass washer, ice maker, RO water system, compressed air system, and vacuum system (collectively, "Lab Systems"), (ii) Tenant will not use the Lab Systems during the Term, and (iii) the Lab Systems shall remain in their current location within the Expansion Premises during the Term and shall not be removed from the Expansion Premises or relocated within the Expansion Premises except as otherwise stated in this paragraph. By no later than the Expansion Premises Commencement Date, Landlord shall take such action as it deems necessary to secure the Lab Systems. From and after the Expansion Premises Commencement Date, Tenant shall have no obligation to maintain service contracts on the Lab Systems, but shall be responsible for repairing or replacing any Lab Systems damaged by Tenant or any Tenant Party. On the expiration or earlier termination of the Term, Tenant shall surrender the Lab Systems to Landlord in their then current condition, ordinary wear and tear and damage by Tenant or any Tenant Party excluded; provided, however, that (A) Tenant shall have the right, at Tenant’s expense and upon not less than 120 days’ advance notice to Landlord, to remove and dispose of all or some of the Lab Systems, which removal and disposal shall be performed in a good and workmanlike manner in accordance with applicable Legal Requirements, and (B) during such 120 day period, Landlord shall have the superior right to sell all or any of the Lab Systems and, in the event of any such sale, Landlord and its agents shall at Landlord’s expense remove such Lab Systems (such removal shall be performed in a good and workmanlike manner in accordance with applicable Legal Requirements), and Landlord shall at its expense promptly repair any damage caused by or occasioned as a result of such removal, including capping off any connections behind the walls of the Premises and repairing any holes. If Tenant exercises its right to remove and dispose of all or any of the Lab Systems as described in this paragraph, Tenant shall at its expense promptly repair any damage caused by or occasioned as a result of such removal, including capping off any connections behind the walls of the Premises and repairing any holes.
2. **Amendment to Section 21 (e) (Suspension of Funding/Performance).** Section 21(e) of the Lease is hereby amended by deleting that provision in its entirety and replacing it with the following new Section 21(e):

   (e) **Suspension of Funding/Performance.** Upon a Default by Tenant hereunder and during the continuance thereof, Landlord shall have the right to suspend funding of any TI Allowance, the Expansion Premises TI Allowance, the HVAC Allowance, or the performance of Landlord’s Work (and such suspension shall constitute a Tenant Delay [as defined in Exhibit C-1 attached hereto]).

4. **Miscellaneous.**

   a. This Fourth Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This Fourth Amendment may be amended only by an agreement in writing, signed by the parties hereto.
b. This Fourth Amendment is binding upon and shall inure to the benefit of the parties hereto, their respective agents, employees, representatives, officers, directors, divisions, subsidiaries, affiliates, assigns, heirs, successors in interest and shareholders.

c. This Fourth Amendment may be executed in 2 or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000), or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Fourth Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

d. Tenant represents and warrants to Landlord that Tenant has not dealt with any broker, agent, or other person (collectively, “Broker”) in connection with this Fourth Amendment and that no Broker brought about this transaction. Tenant hereby agrees to indemnify and hold Landlord harmless from and against any claims by any Broker claiming a commission or other form of compensation by virtue of having dealt with Tenant with regard to this Fourth Amendment.

e. Except as amended and/or modified by this Fourth Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchangeable by this Fourth Amendment. In the event of any conflict between the provisions of this Fourth Amendment and the provisions of the Lease, the provisions of this Fourth Amendment shall prevail. Regardless of whether specifically amended by this Fourth Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Fourth Amendment.

[SIGNATURES APPEAR ON NEXT PAGE]
IN WITNESS WHEREOF, the parties hereto have executed this Fourth Amendment under seal as of the day and year first above written.

TENANT:

KITE PHARMA, INC.,
a Delaware corporation

By: /s/ Tim Moore (SEAL)
Name: Tim Moore
Title: EVP Technical Operations

Approved by Legal Department

By: /s/ Illegible

LANDLORD:

TECH PARK 270 III, LLC,
a Maryland limited liability company

By: ARE-MM Tech Park 270 III, LLC,
a Delaware limited liability company, managing member

By: ARE-930 Clopper Road, LLC,
a Delaware limited liability company, managing member

By: Alexandria Real Estate Equities, L.P.,
a Delaware limited partnership, managing member

By: ARE-QRS CORP.,
a Maryland corporation, general partner

By: /s/ Jackie Clem (SEAL)
Name: Jackie Clem
Title: Senior Vice President
RE Legal Affairs

Signature: 
Email: [***]

Copyright © 2012. Alexandria Real Estate Equities, Inc. ALL RIGHTS RESERVED. Confidential and Proprietary. Do Not Copy or Distribute. Alexandria and Alexandria Logo are registered trademarks of Alexandria Real Estate Equities, Inc.
NON-EXCLUSIVE LICENSE AGREEMENT

by and between

ACUITAS THERAPEUTICS, INC.

and

BIOTECH RNA PHARMACEUTICALS GMBH

dated

April 7, 2020
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. DEFINITIONS</td>
<td>1</td>
</tr>
<tr>
<td>2. LICENSE GRANTS; TECHNOLOGY TRANSFER</td>
<td>8</td>
</tr>
<tr>
<td>2.1 Licenses by Acuitas</td>
<td>8</td>
</tr>
<tr>
<td>2.2 Option to Convert Non-exclusive License</td>
<td>8</td>
</tr>
<tr>
<td>2.3 Sublicensing Rights</td>
<td>8</td>
</tr>
<tr>
<td>2.4 Technology Transfer</td>
<td>9</td>
</tr>
<tr>
<td>2.5 Updates to Appendix 1.1</td>
<td>9</td>
</tr>
<tr>
<td>2.6 Documents and Declaration</td>
<td>9</td>
</tr>
<tr>
<td>3. LICENSE LIMITATIONS</td>
<td>9</td>
</tr>
<tr>
<td>4. PAYMENTS AND ROYALTIES</td>
<td>9</td>
</tr>
<tr>
<td>4.1 Milestone Payments</td>
<td>10</td>
</tr>
<tr>
<td>4.2 Royalties</td>
<td>11</td>
</tr>
<tr>
<td>4.3 Payment Terms</td>
<td>12</td>
</tr>
<tr>
<td>5. OWNERSHIP AND INVENTORSHIP OF IP</td>
<td>13</td>
</tr>
<tr>
<td>6. PATENT PROSECUTION AND MAINTENANCE</td>
<td>13</td>
</tr>
<tr>
<td>6.1 Generally</td>
<td>14</td>
</tr>
<tr>
<td>6.2 Election Not to Prosecute or Maintain or Pay Patent Costs</td>
<td>14</td>
</tr>
<tr>
<td>6.3 Regulatory Exclusivity Periods</td>
<td>15</td>
</tr>
<tr>
<td>6.4 Cooperation</td>
<td>15</td>
</tr>
<tr>
<td>7. PATENT ENFORCEMENT AND DEFENSE</td>
<td>15</td>
</tr>
<tr>
<td>7.1 Notice</td>
<td>15</td>
</tr>
<tr>
<td>7.2 Enforcement and Defense</td>
<td>15</td>
</tr>
<tr>
<td>8. CONFIDENTIALITY</td>
<td>17</td>
</tr>
<tr>
<td>8.1 Confidential Information</td>
<td>17</td>
</tr>
<tr>
<td>8.2 Restrictions</td>
<td>17</td>
</tr>
<tr>
<td>8.3 Exceptions</td>
<td>17</td>
</tr>
<tr>
<td>8.4 Permitted Disclosures</td>
<td>18</td>
</tr>
<tr>
<td>8.5 Return of Confidential Information</td>
<td>18</td>
</tr>
<tr>
<td>8.6 Publications</td>
<td>19</td>
</tr>
<tr>
<td>8.7 Terms of this License Agreement; Publicity</td>
<td>19</td>
</tr>
<tr>
<td>Section</td>
<td>Page</td>
</tr>
<tr>
<td>---------</td>
<td>------</td>
</tr>
<tr>
<td>9. WARRANTIES; LIMITATIONS OF LIABILITY; INDEMNIFICATION</td>
<td>19</td>
</tr>
<tr>
<td>9.1 Representations and Warranties</td>
<td>19</td>
</tr>
<tr>
<td>9.2 Additional Representations of Acuitas</td>
<td>19</td>
</tr>
<tr>
<td>9.3 Disclaimers</td>
<td>20</td>
</tr>
<tr>
<td>9.4 No Consequential Damages</td>
<td>20</td>
</tr>
<tr>
<td>9.5 Performance by Others</td>
<td>21</td>
</tr>
<tr>
<td>9.6 Indemnification</td>
<td>21</td>
</tr>
<tr>
<td>9.7 Insurance</td>
<td>23</td>
</tr>
<tr>
<td>10. TERM AND TERMINATION</td>
<td>23</td>
</tr>
<tr>
<td>10.1 Term</td>
<td>23</td>
</tr>
<tr>
<td>10.2 Termination by Acuitas</td>
<td>23</td>
</tr>
<tr>
<td>10.3 Termination by BioNTech</td>
<td>24</td>
</tr>
<tr>
<td>10.4 Termination Upon Bankruptcy</td>
<td>24</td>
</tr>
<tr>
<td>10.5 Effects of Termination</td>
<td>25</td>
</tr>
<tr>
<td>10.6 Survival</td>
<td>25</td>
</tr>
<tr>
<td>11. GENERAL PROVISIONS</td>
<td>25</td>
</tr>
<tr>
<td>11.1 Dispute Resolution</td>
<td>25</td>
</tr>
<tr>
<td>11.2 Cumulative Remedies and Irreparable Harm</td>
<td>26</td>
</tr>
<tr>
<td>11.3 Relationship of Parties</td>
<td>26</td>
</tr>
<tr>
<td>11.4 Compliance with Law</td>
<td>26</td>
</tr>
<tr>
<td>11.5 Governing Law</td>
<td>27</td>
</tr>
<tr>
<td>11.6 Counterparts; Facsimiles</td>
<td>27</td>
</tr>
<tr>
<td>11.7 Headings</td>
<td>27</td>
</tr>
<tr>
<td>11.8 Waiver of Rule of Construction</td>
<td>27</td>
</tr>
<tr>
<td>11.9 Interpretation</td>
<td>27</td>
</tr>
<tr>
<td>11.10 Binding Effect</td>
<td>27</td>
</tr>
<tr>
<td>11.11 Assignment</td>
<td>27</td>
</tr>
<tr>
<td>11.12 Notices</td>
<td>27</td>
</tr>
<tr>
<td>11.13 Amendment and Waiver</td>
<td>28</td>
</tr>
<tr>
<td>11.14 Severability</td>
<td>28</td>
</tr>
<tr>
<td>11.15 Entire Agreement</td>
<td>28</td>
</tr>
<tr>
<td>11.16 Force Majeure</td>
<td>28</td>
</tr>
</tbody>
</table>
### List of Appendices

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix 1.1</td>
<td>Patents within the Acuitas LNP Technology as of the License Agreement Effective Date</td>
</tr>
<tr>
<td>Appendix 1.17</td>
<td>Dual Improvement Patents</td>
</tr>
<tr>
<td>Appendix 1.23</td>
<td>Jointly Owned Patents</td>
</tr>
<tr>
<td>Appendix 1.53</td>
<td>Description of the Target(s)</td>
</tr>
<tr>
<td>Appendix 2.4</td>
<td>Technology Transfer Agreement</td>
</tr>
<tr>
<td>Appendix 9.2</td>
<td>Exceptions to Acuitas’ Representations and Warranties in Section 9.2</td>
</tr>
</tbody>
</table>
This License Agreement ("License Agreement"), dated as of April 7, 2020 (the "License Agreement Effective Date"), is made by and between Acuitas Therapeutics Inc., a British Columbia corporation ("Acuitas"), and BioNTech RNA Pharmaceuticals GmbH, a German corporation ("BioNTech"). Each of Acuitas and BioNTech may be referred to herein as a "Party," or together as the "Parties."

WHEREAS, Acuitas has proprietary LNP Technology (as defined below);

WHEREAS, BioNTech has expertise and intellectual property relating to mRNA Constructs (as defined below) as well as to formulation development including non-clinical testing and GMP manufacturing;

WHEREAS, Acuitas and BioNTech are parties to that certain Development and Option Agreement (dated July 10, 2017) (the "Development and Option Agreement") pursuant to which BioNTech has options to take licenses under the Acuitas LNP Technology (as defined below) with respect to BioNTech’s mRNA Constructs; and

WHEREAS, pursuant to the terms of the Development and Option Agreement, BioNTech has exercised an option with respect to the Target (as defined below) and the Parties are now entering into a licensing arrangement whereby BioNTech will have a license under the Acuitas LNP Technology to develop and commercialize Licensed Products (as defined below) based on such Target.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the amount and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. Definitions
The following terms and their correlatives will have the following meanings:

1.1 "Acuitas LNP Technology" means any and all LNP Technology Controlled by Acuitas or any of its Affiliates as of the License Agreement Effective Date or at any time during the Term, including Acuitas’ right and interest in any Technology created, conceived or reduced to practice under the Development and Option Agreement and necessary or useful for the research, development, manufacturing and commercialization of Licensed Products. Unless otherwise set forth herein, Acuitas LNP Technology will exclude Jointly Owned Patents and Dual Improvement Patents.

1.2 "Acuitas Indemnitiees" has the meaning set forth in Section 9.6(a).

1.3 "Affiliate" of a person or entity means any other entity which (directly or indirectly) is controlled by, controls or is under common control with such person or entity. For the purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to an entity will mean (i) in the case of a corporate entity, direct or indirect ownership of voting securities entitled to cast at least fifty percent (50%) of the votes in the election of directors or (ii) in the case of a non-corporate entity, direct or indirect ownership of at least fifty percent (50%) of the equity interests with the voting power to direct the management and policies of such entity, provided that if local Law restricts foreign ownership, control will be established by direct or indirect ownership of the maximum ownership percentage that may, under such local Law, be owned by foreign interests.

1
1.4 [***]
1.5 “cGMP” means current Good Manufacturing Practices as specified in the U.S. C.F.R., ICH Guideline Q7A, or equivalent Laws of an applicable Regulatory Authority at the time of manufacture.
1.6 “Calendar Quarter” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.
1.7 “Change of Control” with respect to Acuitas, shall be deemed to have occurred if during the Term (i) any person or entity is or becomes the “beneficial owner”, directly or indirectly, of shares of capital stock or other interests (including partnership interests) of Acuitas then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions of Acuitas representing fifty percent (50%) or more of the total voting power of all outstanding classes of voting stock of Acuitas or has the power, directly or indirectly, to elect a majority of the members of the Acuitas’ board of directors, or similar governing body, or (ii) Acuitas enters into a merger, consolidation or similar transaction with another person or entity; or (iii) Acuitas sells or transfers to any Third Party, in one (1) or more related transactions, properties or assets representing all or substantially all of Acuitas’ consolidated total assets to which this Agreement relates; or (iv) the holders of capital stock of Acuitas approve a plan or proposal for the liquidation or dissolution of Acuitas’.
1.8 “Combination Product” means a Licensed Product that is combined and sold together (but not, for avoidance of doubt, formulated together) with at least one additional active ingredient/product other than a Licensed Product. Drug delivery vehicles, adjuvants, and excipients shall not be deemed to be “active ingredients”, except in the case where such delivery vehicle, adjuvant, or excipient is recognized as an active ingredient in accordance with 21 C.F.R. 210.3(b)(7) or equivalent Laws in other jurisdictions, provided however, [***]
1.9 “Competitive Product” shall mean a product that is, or can reasonably be, used for the same Indication as a Licensed Product.
1.10 “Indication” shall mean an individual disease or clinical condition with respect to which at least one adequate and well controlled study is required to support inclusion of such disease or condition in the indication statement of an FDA approved package insert for a Licensed Product.
1.11 “Confidential Information” has the meaning set forth in Section 8.1.
1.12 “Control” or “Controlled” means, with respect to any Know-How or Patent, the possession (whether by ownership or license, other than by a license or sublicense granted pursuant to this License Agreement or the Development and Option Agreement) by Acuitas or its Affiliates of the ability to grant to BioNTech a license or access to such Know-How or Patent as provided herein to such item, without violating the terms of any agreement or other arrangement with any Third Party and without owing any milestone, royalty or other monetary obligations to a Third Party.

1.13 “Covered Product” means a Licensed Product covered by one or more Valid Claims of the Acuitas LNP Technology.

1.14 “Covered”, with reference to (a) a Patent, means that the manufacture, development or commercialization of a Licensed Product would infringe a Valid Claim of such Patent in the country in which such activity occurs; and (b) Know-How, means that the manufacture, development or commercialization of a Licensed Product incorporates or embodies such Know-How.

1.15 “Development and Option Agreement” has the meaning set forth in the Preamble.

1.16 “Disclosing Party” has the meaning set forth in Section 8.1

1.17 “Dual Improvement Patents” means the Patents listed in Appendix 1.17 hereto, as amended from time to time.

1.18 “Field of Use” means use of Licensed Product for human therapeutic and prophylactic applications.

1.19 “First Commercial Sale” means the first sale for use or consumption of any Licensed Product in a country after all required Regulatory Approvals for commercial sale of such Licensed Product have been obtained in such country.

1.20 “Fusion Protein” [***]

1.21 “Indemnification Claim Notice” has the meaning set forth in Section 9.6(c).

1.22 “Indemnified Party” has the meaning set forth in Section 9.6(c).

1.23 “Jointly Owned Patents” means the Patents listed in Appendix 1.23 hereto, as amended from time to time.

1.24 “Know-How” means all commercial, technical, scientific and other know-how and information, trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, manufacturing and quality control data and know-how, including study designs and protocols), in all cases, provided it is confidential and proprietary, and regardless of whether patentable, in written, electronic or any other form.
1.25 “Law” or “Laws” means all laws, statutes, rules, regulations, orders, judgments, or ordinances having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision.
1.26 “License Agreement” has the meaning set forth in the Preamble.
1.27 “License Agreement Effective Date” has the meaning set forth in the Preamble.
1.28 “Licensed Product(s)” means [***] product(s) consisting of Lipid Nanoparticles (LNP) containing [***] mRNA Constructs [***] where such product is derived from, is based on, or utilizes any Acuitas LNP Technology. For the avoidance of doubt, the term “Licensed Product” in respect of the Target [***].
1.29 “LNP Technology” means Technology that claims, embodies or incorporates delivery systems (and components thereof) based on or incorporating lipid nanoparticles (LNP).
1.30 “LNP Technology Patent(s)” means Patents comprised in the Acuitas LNP Technology, including any future Patent which will become part of the Acuitas LNP Technology during the Term and further including Acuitas’ rights in the Jointly Owned Patents, unless otherwise set forth herein.
1.31 “Losses” has the meaning set forth in Section 9.6(a).
1.32 “Major Market Countries” means Canada, United States, Japan, France, Germany, Spain, Italy, or United Kingdom.
1.33 “mRNA Construct” [***]
1.34 “mRNA Technology” means Technology that claims, embodies or incorporates expression systems (and components thereof), based on or incorporating mRNA.
1.35 “Milestones” means the milestones payable pursuant to Section 4. 1.36 “Milestone Event” has the meaning set forth in Section 4.1. 1.37 “Milestone Payment” has the meaning set forth in Section 4.1.
1.38 “Net Sales” means, with respect to any Licensed Product, (***)

(a) [***]
(b) [***]
(c) [***]
(d) [***]
(e) [***]
(f) [***]
(g) [***]

1.39 “Patent(s)” means an (i) issued patent, a patent application, and a future patent issued from any such patent application, (ii) a future patent issued from a patent application filed in any country worldwide which claims priority from a patent or patent application of (i), and (iii) any additions, divisions, continuations, continuations-in-part, invention certificates, substitutions, reissues, reexaminations, extensions, registrations, utility models, supplementary protection certificates and renewals based on any patent or patent application under (i) or (ii), but not including any rights that give rise to regulatory exclusivity periods (other than supplementary protection certificates, which will be treated as “Patents” hereunder).
1.40 “Patent Costs” means the reasonable, documented, out-of-pocket costs and expenses paid to outside legal counsel, and filing and maintenance expenses, actually and reasonably incurred by a Party in prosecuting and maintaining Patents and enforcing and defending them.

1.41 “Phase 1 Study” means a human clinical trial of a Licensed Product in any country, the primary purpose of which is the determination of safety and which may include the determination of pharmacokinetic and/or pharmacodynamic profiles in healthy individuals or a diseased patient population. A Phase 1 Study in a diseased patient population may include, in addition to primary determination of safety, dose exploration and a determination of preliminary efficacy of a product in the target patient population. For clarity, a particular human clinical trial of a Licensed Product will not be considered both a Phase 1 Study and a Phase 2 Study for the purposes of Milestone payments under Section 4.1.

1.42 “Phase 2 Study” means a human clinical trial of a Licensed Product in any country, and which is: (a) a human clinical trial (other than a Phase 1 Study) in which the primary purpose is dose exploration, dose response, duration of effect, kinetics or preliminary efficacy and safety of a product in the target patient population, or (b) a controlled dose-ranging clinical trial to evaluate further the efficacy and safety of such product in the target patient population and to define the optimal dosing regimen.

1.43 “Phase 3 Study” means a human clinical trial of a Licensed Product in any country, and which is: (a) a controlled study of a product in the target patient population of the efficacy and safety of such product which is prospectively designed to demonstrate statistically whether such product is effective and safe for use in a particular indication in a manner sufficient to obtain Regulatory Approval to market such product.

1.44 “Pre-Existing Restrictions” means, with respect to a Target, that (a) [***] (“Pre-Existing Third Party Restrictions”), or (b) [***] (“Pre-Existing Internal Restrictions”).

1.45 “Receiving Party” has the meaning set forth in Section 8.1.

1.46 “Regulatory Approval” means, with respect to a country or extra-national territory, any and all approvals (including BLAs and MAAs), licenses, registrations or authorizations of any Regulatory Authority necessary in order to commercially distribute, sell or market a product in such country or some or all of such extra-national territory, including any pricing or reimbursement approvals.

1.47 “Regulatory Authority” means any national (e.g., the FDA), supra-national (e.g., the EMA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental authority, in any jurisdiction in the world, involved in the granting of Regulatory Approval.

1.48 “[***] Target” means the [***]

1.49 “Royalty Term” has the meaning set forth in Section 4.2(d).
1.50 “BioNTech Indemnitees” has the meaning set forth in Section 9.6(b).
1.51 “Solely Owned IP” has the meaning set forth in Article 5.
1.52 “Sublicensee” means any Third Party that is granted a sublicense as permitted by Section 2.2, either directly by BioNTech or its Affiliates or indirectly by any other Sublicensee hereunder.
1.53 “Target” means the protein described in Appendix 1.53 and includes: (a) [***] naturally occurring human protein [***].
1.54 “Technology” means collectively Patents and Know-How. 1.55 “Term” has the meaning set forth in Section 10.1.
1.56 “Territory” means worldwide.
1.57 “Third Party” means any person or entity other than BioNTech, Acuitas and their respective Affiliates.
1.58 “Third Party Claims” has the meaning set forth in Section 9.6(a).
1.59 “Vaccine” means any product primarily intended (i) to elicit an adaptive immune response in the recipient against a specific disease-causing organism or malignancy as the result of presentation of antigen(s) associated with the disease-causing organism or malignancy; or (ii) to provide passive immune protection against a specific disease-causing organism.
1.60 “Vaccine Target” means Covid-19 Target as described in Appendix 1.53.
1.61 “Valid Claim” means, with respect to a particular country, any claim of (i) an issued and unexpired Patent; or (ii) a pending Patent claim, [***]
2. License Grants; Technology Transfer

2.1 Licenses by Acuitas. Subject to the terms and conditions of this License Agreement, Acuitas hereby grants to BioNTech and its Affiliates (i) a non-exclusive, non-transferable license, with the right to sublicense only as permitted by Section 2.3(b), under the Acuitas LNP Technology, to develop, have developed, make, have made, use and have used, sell, offer for sale, have sold and import and have imported Licensed Products in the Field of Use in the Territory and (ii) an exclusive, non-transferable license, with the right to sublicense only as permitted by Section 2.3(b), under the Jointly Owned Program Patents, and any Dual Improvement Patents owned by Acuitas, to develop, have developed, make, have made, use and have used, sell, offer for sale, have sold and import and have imported Licensed Products within the scope of allowed and/or issued claims within any Major Market Country (whether or not expired) within the BioNTech mRNA Technology in the Field of Use in the Territory. [***]

2.2 Option to Convert Non-exclusive License. BioNTech will have a limited option to convert the non-exclusive license granted pursuant to Section 2.1 to an exclusive license. BioNTech will notify Acuitas and the Escrow Agent in writing of its desire to exercise the exclusive license option ("Conversion Option Notice") and pay to Acuitas an escrow fee of [***] dollars (U.S.$ [***]). The Escrow Agent - on behalf of Acuitas - will review the Conversion Option Notice provided by BioNTech hereunder to determine whether or not any such proposed Target is on the Restricted Target List as of the date of such Option Conversion Notice. If the Target is subject to Pre-existing Restrictions, the Escrow Agent will notify BioNTech that the license set forth in Section 2.1 may not be converted to an exclusive license. If the Target is not subject to Pre-existing Restrictions, the Escrow Agent will notify BioNTech that the license set forth in Section 2.1 may be converted to an exclusive license upon BioNTech's delivery of a signed Exclusive License Agreement in the form attached hereto as Exhibit 2.2 and payment of a conversion fee equal to the difference between the nonexclusive and exclusive option fee under the Development and Option Agreement ([***] dollars (U.S.$ [***])) plus (the difference between any milestone fees paid under the nonexclusive license prior to the Conversion Option Notice and the milestone fees for such events under an exclusive license).

2.3 Sublicensing Rights.

(a) Transfer. The license granted in Section 2.1 [and option set forth in Section 2.2] is transferable only upon a permitted assignment of this License Agreement in accordance with Section 11.11.

(b) BioNTech Sublicenses. The licenses granted in Section 2.1 may be sublicensed (with the right to sublicense through multiple tiers), in full or in part, by BioNTech, its Affiliates or Sublicensees to Third Parties provided, that for any sublicense to Third Parties:

(i) Each sublicense will be in writing and on terms consistent with and subject to the terms of this License Agreement,

(ii) BioNTech will provide Acuitas with a copy of any sublicense agreement with a Sublicensee within [***] days of execution thereof, which sublicense agreement may be redacted as necessary to protect commercially sensitive information and shall be treated as BioNTech Confidential Information hereunder.
(iii) BioNTech will be responsible for any and all obligations of such Sublicensee as if such Sublicensee were BioNTech hereunder; and

(iv) Any sublicense granted by BioNTech to any rights licensed to it hereunder shall terminate immediately upon the termination of the license from Acuitas to BioNTech and its Affiliates with respect to such rights, provided that such sublicensed rights shall not terminate if, as of the effective date of such termination pursuant to Sections 10.2, 10.3(a) or 10.4, a Sublicensee is not in material default of its obligations under its sublicense agreement, and within [***] days of such termination and a written notice by Acuitas and disclosure of this License Agreement to the Sublicensee, the Sublicensee agrees in writing to be bound directly to Acuitas under a license agreement substantially similar to this License Agreement with respect to the rights sublicensed hereunder, substituting such Sublicensee for BioNTech.

(c) **Subcontractors.** For clarity purposes, BioNTech is entitled to engage contract research organizations and contract manufacturing organizations for the development and manufacture of Licensed Products on behalf of BioNTech. To the extent such contract organizations require a license to perform such subcontracted activities under applicable Laws, BioNTech is entitled to grant a limited license without an obligation to meet the conditions of Section 2.2(b)(i) and (iv).

2.4 **Technology Transfer.** After the License Agreement Effective Date Acuitas will conduct a single full transfer of Acuitas LNP Technology to BioNTech and/or its designee(s) (which designee(s) may be an Affiliate or a Third Party cGMP manufacturer) as required for the applicable transferee of the then-current process. The technology transfer activities, the rights and obligations of the Parties, the reimbursement of Acuitas for the technology transfer activities, and the rights and licenses to any Technology generated in the course of the technology transfer transfer will be as set forth in the Technology Transfer Agreement becoming effective on the License Agreement Effective Date and included in Appendix 2.4.

2.5 **Updates to Appendix 1.1.** Acuitas shall notify BioNTech at least once every [***] months of Patents that are added to the Acuitas LNP Technology following the License Agreement Effective Date or any Patents that have been abandoned or discontinued in accordance with the terms of this License Agreement. Appendix 1.1 shall be automatically updated to include any such added or deleted Patents.

2.6 **Documents and Declarations.** Acuitas shall execute all documents, give all declarations regarding the licenses granted hereunder and reasonably cooperate with BioNTech to the extent such documents, declarations and/or cooperation are required for the recording or registration of the licenses granted hereunder at the various patent offices in the Territory for the benefit of BioNTech, its Affiliates or their Sublicensees.

3. **License Limitations.** No licenses or other rights are granted by Acuitas hereunder to use any trademark, trade name, trade dress or service mark owned or otherwise Controlled by Acuitas or any of its Affiliates. All licenses and other rights are or shall be granted only as expressly provided in this License Agreement, and no other licenses or other rights is or shall be created or granted by either Party hereunder by implication, estoppel or otherwise.

4. **Payments and Royalties.**

Payment to Acuitas upon the first occurrence of each of the milestone events (each, a “Milestone Event”) by a Licensed Product as set forth below in this Section 4.1. BioNTech will notify Acuitas of the.
## 4.1 Milestone Payments

BioNTech will make milestone payments (each, a “Milestone achievement of each Milestone Event within [***] business days of such achievement. Each Milestone Payment will be payable to Acuitas by BioNTech within [***] days of the achievement of the specified Milestone Event and such payments when owed or paid will be non-refundable and non-creditable. If one or more of the Milestone Events set forth below are not achieved or not required for any reason, the payment for such skipped Milestone Event will be due at the same time as the payment for the next achieved Milestone Event.

<table>
<thead>
<tr>
<th>Milestone Event</th>
<th>Milestone Payment For Covered Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
</tbody>
</table>


4.2 Royalties.

(a) Royalty. Subject to the remainder of this Section 4.2, on a country-by-country basis and a Licensed Product-by-Licensed Product basis,

(i) [***] BioNTech will pay to Acuitas a royalty of [***]% Net Sales.

(b) Third Party Royalty Payments. If BioNTech or its Affiliate or Sublicensee, in its reasonable judgment, considers it necessary or useful to obtain a license from any Third Party that Covers a Licensed Product in order to develop, manufacture or commercialize such Licensed Product the amount of BioNTech’s royalty obligations under Sections 4.1(a) will be reduced by [***] percent ([***]%) of the amount of the royalty payments made to such Third Party (“Third Party Royalty Payments”), provided, however, [***] For avoidance of doubt, Third Party Royalty Payments will include payments by BioNTech in connection with Acuitas sublicenses under Section 2.2.

(c) [***]

(d) Term. The royalty term (“Royalty Term”) shall expire on a country-by-country and Licensed Product-by-Licensed Product basis, on the last to occur of (i) expiration of the last to expire Valid Claim in the Acuitas LNP Technology that, but for the license described herein from Acuitas to BioNTech for the applicable Licensed Product, is infringed by the making, using or sale of such Licensed Product, (ii) expiration of any period of data exclusivity, market exclusivity or supplemental protection certificates covering the Licensed Product in such country, and (iii) [***] years after First Commercial Sale of Licensed Product in such country, provided [***]. For the avoidance of doubt, upon exhaustion of the obligation to pay Royalties to Acuitas as set forth above the continued use of Acuitas Know-How comprised in the LNP Technology for the development, manufacture and/or sale of the Licensed Product shall not, in and of itself, obligate BioNTech to pay further royalties to Acuitas. Thereafter, BioNTech’s license under Section 2.1 will become irrevocable, fully paid-up and royalty-free on a country-by-country and Licensed Product-by-Licensed Product basis.
4.3 Payment Terms.

(a) Manner of Payment. All payments to be made by BioNTech hereunder will be made in U.S. dollars by wire transfer to such bank account as Acuitas may designate.

(b) Records and Audits. BioNTech shall keep, and shall cause each of its Affiliates and Sublicensees, as applicable, to keep adequate books and records of accounting for the purpose of calculating all royalties payable to Acuitas hereunder. For the [***] years next following the end of the calendar year to which each shall pertain, such books and records of accounting (including those of BioNTech’s Affiliates) shall be kept at each of their principal places of business and shall be open for inspection at reasonable times and upon reasonable notice by an independent certified accountant selected by Acuitas, and which is reasonably acceptable to BioNTech, for the sole purpose of inspecting the royalties due to Acuitas under this License Agreement. In no event shall such inspections be conducted hereunder more frequently than once every [***] months. Such accountant must have executed and delivered to BioNTech and its Affiliates, a confidentiality agreement as reasonably requested by BioNTech, which shall include provisions limiting such accountant’s disclosure to Acuitas to only the results and basis for such results of such inspection. The results of such inspection, if any, shall be binding on both Parties. Any underpayments shall be paid by BioNTech within [***] days of notification of the results of such inspection. Any overpayments shall be fully creditable against amounts payable in subsequent payment periods. Acuitas shall pay for such inspections, except that in the event there is any upward adjustment in aggregate royalties payable for any calendar year shown by such inspection of more than [***] percent ([***]%s) of the amount paid, BioNTech shall reimburse Acuitas for any reasonable out-of-pocket costs of such accountant.

(c) Reports and Royalty Payments. For as long as royalties are due under Section 4.2, BioNTech shall furnish to Acuitas a written report for each Calendar Quarter, showing the amount of Net Sales of Licensed Products and royalty due for such Calendar Quarter. Reports shall be provided within [***] ([***]) days of the end of the Calendar Quarter for Net Sales generated by BioNTech and its Affiliates, and within [***] ([***]) days of the end of the Calendar Quarter for Net Sales generated by Sublicensees. Royalty payments for each Calendar Quarter shall be due at the same time as the last such written report for the Calendar Quarter. The report shall include, at a minimum, the following information for the applicable Calendar Quarter, each listed by Licensed Product and by country of sale: (i) [***] (ii) [***] (iii) [***] and (v) [***]. All such reports shall be treated as Confidential Information of BioNTech. [***].
(d) **Currency Exchange.** With respect to Net Sales invoiced in U.S. dollars, the Net Sales and the amounts due to Acuitas hereunder will be expressed in U.S. dollars. With respect to Net Sales invoiced in a currency other than U.S. dollars, payments will be calculated based on standard methodologies employed by BioNTech or its Affiliates or Sublicensees for consolidation purposes for the Calendar Quarter for which remittance is made for royalties.

(c) **Withholding Taxes.** BioNTech may withhold from payments due to Acuitas amounts for payment of any withholding tax that is required by Law to be paid to any taxing authority with respect to such payments. BioNTech will provide Acuitas all relevant documents and correspondence, and will also provide to Acuitas any other cooperation or assistance on a reasonable basis as may be necessary to enable Acuitas to claim exemption from such withholding taxes and to receive a refund of such withholding tax or claim a foreign tax credit. BioNTech will give proper evidence from time to time as to the payment of any such tax. The Parties will cooperate with each other in seeking deductions under any double taxation or other similar treaty or agreement from time to time in force. Such cooperation may include BioNTech making payments from a single source in the U.S., where possible. Apart from any such permitted withholding and those deductions expressly included in the definition of Net Sales, the amounts payable by BioNTech to Acuitas hereunder will not be reduced on account of any taxes, charges, duties or other levies.

(f) **Taxes on Income.** Except as otherwise set forth in this Section 4.3, 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.

(g) **Blocked Payments.** In the event that, by reason of applicable law in any country, it becomes impossible or illegal for BioNTech or its Affiliates or Sublicensees to transfer, or have transferred on its behalf, payments owed to Acuitas hereunder, BioNTech will promptly notify Acuitas of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country to the credit of Acuitas in a recognized banking institution designated by Acuitas or, if none is designated by Acuitas within a period of [***] days, in a recognized banking institution selected by BioNTech or its Affiliate or Sublicensee, as the case may be, and identified in a written notice given to Acuitas.

(h) **Interest Due.** If any payment due to Acuitas under this License Agreement is overdue (and is not subject to a good faith dispute), then BioNTech will pay interest thereon (before and after any judgment) at an annual rate of the lesser of [***] percent ([***]% or [***]) above the prime rate as reported in The Wall Street Journal, Eastern Edition, and [***], such interest to run from the date upon which payment of such sum became due until payment thereof in full together with such interest.

(i) **Mutual Convenience of the Parties.** The royalty and other payment obligations set forth hereunder have been agreed to by the Parties for the purpose of reflecting and advancing their mutual convenience, including the ease of calculating and paying royalties and other amounts to Acuitas.

5. **Ownership and Inventorship of IP.** As between the Parties, each Party will own and retain all right, title and interest in and to any and all Know-How and Patents arising therefrom that are discovered, created, conceived, developed or reduced to practice solely by or on behalf of such Party under or in connection with this License Agreement (“Solely Owned IP”). Subject to the licenses hereunder and the other terms and conditions of this License Agreement or any other agreement between the Parties, each Party will be solely responsible for the prosecution and maintenance, and the enforcement and defense, of any Patents within its Solely Owned IP.
6. Patent Prosecution and Maintenance

6.1 Generally. As between the Parties and subject to Section 6.2 below, Acuitas (or its Third Party licensor, if any) will have the sole right, at its sole costs, to prosecute and maintain Acuitas LNP Technology Patents. Upon filing, Acuitas will provide BioNTech with copies of all applications for all such LNP Technology Patents, and will keep BioNTech timely updated about patent applications intended for grant. If BioNTech deems it necessary to file a divisional application before grant of the patent but Acuitas elects not to file such a divisional application, BioNTech will have the right to request the filing on its own costs under the provisions of Section 6.2(a). The Parties will enter into a joint patent prosecution and maintenance agreement with respect to prosecution and maintenance any and all Jointly Owned Patents and the Parties will share equally all costs in connection with such efforts.

6.2 Election Not to Prosecute or Maintain or Pay Patent Costs.

(a) By Acuitas. If Acuitas elects not (i) to file, prosecute or maintain any LNP Technology Patents (including filing a divisional application for any LNP Technology Patents) for which it is responsible under Section 6.1 in any particular country before the applicable filing deadline or continue such activities once filed in a particular country, or (ii) to pay the Patent Costs associated with prosecution or maintenance of any such LNP Technology Patents then in each such case Acuitas will so notify BioNTech, promptly in writing and in good time to enable Acuitas to meet any deadlines by which an action must be taken to preserve such LNP Technology Patent in such country, if BioNTech so requests. Upon receipt of each such notice by Acuitas, BioNTech will have the right, but not the obligation, to notify Acuitas in writing on a timely basis that Acuitas should continue the prosecution and/or maintenance and/or file divisional application of such LNP Technology Patent in the respective country, and thereafter, Acuitas would prosecute and maintain such LNP Technology Patent in such country at the sole direction of BioNTech. Acuitas would make available to BioNTech all documentation and correspondence with respect to such Acuitas LNP Technology Patents, and BioNTech would compensate the reasonable Patent Costs incurred by Acuitas in connection with such efforts, i.e., Patent Costs which Acuitas would not have had incurred if it had elected not to file, prosecute or maintain the respective Acuitas LNP Technology Patent. BioNTech’s license to such Acuitas LNP Technology Patent hereunder under Section 2.1 will be, irrevocable and royalty free, and such Acuitas LNP Technology Patent will thereafter no longer be part of the Acuitas LNP Technology in such country for purposes of this License Agreement. BioNTech is entitled to discontinue the payment of Patent Costs for any LNP Technology Patents at any time, provided that it will so notify Acuitas in writing in time for such discontinuance.

(b) By BioNTech. If BioNTech elects not (i) to file, prosecute or maintain any Jointly Owned Patents for which it is responsible under Section 6.1 in any particular country before the applicable filing deadline or continue such activities once filed in a particular country, or (ii) to pay the Patent Costs associated with prosecution or maintenance of any Jointly Owned Patents then in each such case BioNTech will so notify Acuitas, promptly in writing and in good time to enable BioNTech to meet any deadlines by which an action must be taken to preserve such Jointly Owned Patent in such country at Acuitas’ expense, if Acuitas so requests. Upon receipt of each such notice by BioNTech, Acuitas will have the right, but not the obligation, to notify BioNTech in writing on a timely basis that BioNTech should transfer the prosecution or maintenance of such Jointly Owned Patent to Acuitas and at Acuitas’ sole expense and such LNP Technology Patent will thereafter no longer be part of the Acuitas LNP Technology in such country for purposes of this License Agreement. Acuitas is entitled to discontinue the payment of Patent Costs for any Jointly Owned Patents at any time, provided that it will so notify BioNTech in writing in time for such discontinuance.

6.3 Regulatory Exclusivity Periods. With respect to any Patent listings required for any regulatory exclusivity periods for Licensed Products the Parties will discuss and seek to reach mutual agreement, subject to Applicable Law, on which Acuitas LNP Technology Patents to list. Except where required under Applicable Law, without the written consent of BioNTech, Acuitas will not apply for, and is not authorized under this Agreement to apply for, any Patent listings required for any regulatory exclusivity periods for any Licensed Product. For the avoidance of doubt, Acuitas is not restricted from applying for any Patent listings required for any regulatory exclusivity periods for any product but the Licensed Products.
6.4 Cooperation. Each Party will reasonably cooperate with the other Party in those activities involving the Acuitas LNP Technology Patents set forth in Sections 6.1 to 6.3. Such cooperation includes promptly executing all documents, or requiring inventors, subcontractors, employees and consultants and agents of BioNTech and Acuitas and their respective Affiliates and Sublicensees to execute all documents, as reasonable and appropriate so as to enable such activities in respect of any such Acuitas LNP Technology Patents in any country.


7.1 Notice. To the extent not in breach of an obligation of confidentiality, each Party will promptly notify, in writing, the other Party upon learning of any actual or suspected infringement of any Acuitas LNP Technology Patents by a Third Party, or of any claim of invalidity, unenforceability, or non-infringement of any Acuitas LNP Technology Patents, and will, along with such notice, supply the other Party with any evidence in its possession pertaining thereto.

7.2 Enforcement and Defense.

(a) Enforcement. As between the Parties, Acuitas (or its Third Party licensor, or licensee if any) will have the first right, but not the obligation, to seek to abate any infringement of the Acuitas LNP Technology Patents by a Third Party, or to file suit against any such Third Party for such infringement provided that (i) Acuitas shall bear all the expense of such suit or abatement of infringement, and (ii) BioNTech shall have the first right but not the obligation to take action or bring suit against such Third party infringer with respect to: (A) Jointly Owned Patents; and/or (B) any other LNP Technology Patents that, on the date of first notice of such infringement, are necessary or useful for the research, development, manufacturing and commercialization of Licensed Product but not necessary or useful for the research, development, manufacturing and commercialization of any LNP-comprising product that is exclusively licensed or optioned to a Third Party or is under late stage development by Acuitas; provided that BioNTech shall bear all the expense of such suit or abatement of infringement. If the Party first responsible for such enforcement elects not to take action or to bring suit to prosecute such infringement or to continue such action or suit, it shall notify the other Party of such election within [***] days after become aware of or receipt of the notice of the infringement or after the election to stop any such action or suit. If after the expiration of the [***] days period (or, if earlier, the date upon which the responsible Party provides written notice that it does not plan to bring such action) the responsible Party has neither obtained a discontinuance of infringement nor filed suit against any such Third Party infringer of such Patent, then (i) in the case of an election by Acuitas (or its Third Party licensor, or licensee if any) not to prosecute an infringement of an LNP Technology Patent, BioNTech shall have the right, but not the obligation, to take action or bring suit against such Third Party infringer of such Patents, provided the infringement is with respect to a product related to the Target(s) being the subject of this License Agreement, and further provided that BioNTech shall bear all the expenses of such suit and (ii) in the case of a BioNTech election not to prosecute an infringement of a Jointly Owned Patents or LNP Technology Patent, Acuitas shall have the right, but not the obligation, to take action or bring suit against such Third Party infringer of such Patents, provided that Acuitas shall bear all the expenses of such suit.
(b) **Defense.** As between the Parties, Acuitas (or is Third Party licensor or licensee, if any) will have the first right, but not the obligation, at its sole costs, to defend against a declaratory judgment action or other action challenging any Acuitas LNP Technology Patents, other than: (i) Jointly Owned Patents; and (ii) any other LNP Technology Patents that, on the date of first notice of such action, are not necessary or useful for the research, development, manufacturing and commercialization of any LNP-comprising product that is exclusively licensed or optioned to a Third Party or is under Late Stage Development by Acuitas, and as between the Parties, BioNTech will have the first right, but not the obligation, at its sole costs, to defend against a declaratory judgment action or other action challenging Jointly Owned Patents and/or such other LNP Technology Patents. If the Party first responsible for such defense does not take steps to defend within a commercially reasonable time, or elects not to continue any such defense (in which case it will promptly provide notice thereof to the other Party), then (i) in the case of an election by Acuitas (or its Third Party licensor, or licensee if any) not to defend any LNP Technology Patent, BioNTech shall have the right, but not the obligation, to take defend any LNP Technology Patents that cover Licensed Product and no other product licensed or optioned by Acuitas to a Third Party or commercialized by Acuitas provided that BioNTech shall bear all the expenses of such suit and (ii) in the case of a BioNTech election not to defend the Jointly Owned Patents, Acuitas shall have the right, but not the obligation, to take action or bring suit to defend such Patents, provided that Acuitas shall bear all the expenses of such suit.

(c) **Notwithstanding the foregoing, any response to a Third Party infringer’s counterclaim of invalidity or unenforceability of any Acuitas LNP Technology Patents shall be controlled by the Party who controls the relevant enforcement proceeding pursuant to Section 7.2 (a) unless otherwise mutually agreed by the Parties.**

(d) **Withdrawal, Cooperation and Participation.** With respect to any infringement or defensive action identified above in this Section 7.2 which may be controlled by either BioNTech or Acuitas:

   (i) If the controlling Party ceases to pursue or withdraw from such action, it will promptly notify the other Party (in good time to enable the other Party to meet any deadlines by which any action must be taken to preserve any rights in such infringement or defensive action) and such other Party may substitute itself for the withdrawing Party, shall be granted the right and standing to sue in the other Party’s name, and proceed under the terms and conditions of this Section 7.2.

   (ii) The non-controlling Party will cooperate with the Party controlling any such action (as may be reasonably requested by the controlling Party), including (A) providing access to relevant documents and other evidence, (B) making its and its Affiliates and licensees and Sublicensees and all of their respective employees, subcontractors, consultants and agents available at reasonable business hours and for reasonable periods of time, but only to the extent relevant to such action, and (C) if necessary, by being joined as a party, subject for this clause (C) to the controlling Party agreeing to indemnify such non-controlling Party for its involvement as a named party in such action and paying those Patent Costs incurred by such Party in connection with such joinder. The Party controlling any such action will keep the other Party updated with respect to any such action, including providing copies of all documents received or filed in connection with any such action.

   (iii) Each Party will have the right to participate or otherwise be involved in any such action controlled by the other Party, in each case at the participating (i.e., non-controlling) Party’s sole cost and expense. If a Party elects to so participate or be involved, the controlling Party will provide the participating Party and its counsel with an opportunity to consult with the controlling Party and its counsel regarding the prosecution of such action (including reviewing the contents of any correspondence, legal papers or other documents related thereto), and the controlling Party will take into account reasonable requests of the participating Party regarding such enforcement or defense.
(e) **Settlement.** Neither Party will settle or consent to an adverse judgment in any action described in this Section 7.2 and controlled by such Party, including any judgment which affects the scope, validity or enforcement of any Acuitas LNP Technology Patents involved therein, without the prior written consent of the other Party (such consent not to be unreasonably withheld or delayed).

(f) **Damages.** Unless otherwise agreed by the Parties, all monies recovered upon the final judgment or settlement of any action which may be controlled by either BioNTech or Acuitas and described in Section 7.2(a) or 7.2(b) in each case will be used first to reimburse the controlling Party, and thereafter the non-controlling Party, for each of their out-of-pocket costs and expenses relating to the action, with the balance of any such recovery to be divided as follows:

(i) To the extent such recovery reflects lost profits damages, BioNTech will retain such lost profits recovery, less the amount of royalties payable to Acuitas by treating such lost profits recovery as “Net Sales” hereunder; and

(ii) To the extent such recovery reflects reasonable royalty damages, [***]% to the Party controlling the action and [***]% to the other Party.

8. **Confidentiality.**

8.1 **Confidential Information.** Each Party ("Disclosing Party") may disclose to the other Party ("Receiving Party"), and Receiving Party may acquire during the course and conduct of activities under this License Agreement, certain proprietary or confidential information of Disclosing Party in connection with this License Agreement. The term “Confidential Information” means all information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked as confidential or proprietary, that are disclosed or made available by or on behalf of the Disclosing Party to the Receiving Party in connection with this License Agreement.

8.2 **Restrictions.** During the Term and for [***] years thereafter, Receiving Party will keep all Disclosing Party’s Confidential Information in confidence with the same degree of care with which Receiving Party holds its own confidential information, but in no event less than reasonable care. Receiving Party will not use Disclosing Party’s Confidential Information except for in connection with the performance of its obligations and exercise of its rights under this License Agreement. Receiving Party has the right to disclose Disclosing Party’s Confidential Information without Disclosing Party’s prior written consent to Receiving Party’s Affiliates, and each of their employees, subcontractors, consultants and agents who have a need to know such Confidential Information in order to perform their obligations and exercise their rights under this License Agreement and who are under written obligation to comply with the restrictions on use and disclosure that are no less restrictive than those set forth in this Section 8.2. Receiving Party assumes responsibility for such entities and persons maintaining Disclosing Party’s Confidential Information in confidence and using same only for the purposes described herein.

8.3 **Exceptions.** Receiving Party’s obligation of nondisclosure and the limitations upon the right to use the Disclosing Party’s Confidential Information will not apply to a specific portion of the Disclosing Party’s Confidential Information to the extent that Receiving Party can demonstrate that such portion: (i) was known to Receiving Party or any of its Affiliates prior to the time of disclosure by the Disclosing Party without obligation of confidentiality; (ii) is or becomes public knowledge through no fault or omission of Receiving Party or any of its Affiliates; (iii) is obtained on a non-confidential basis by Receiving Party or any of its Affiliates from a Third Party who to Receiving Party’s knowledge is lawfully in possession thereof and under no obligation of confidentiality to Disclosing Party; or (iv) has been independently developed by or on behalf of Receiving Party or any of its Affiliates without the aid, application or use of Disclosing Party’s Confidential Information.
8.4 Permitted Disclosures. Receiving Party may disclose Disclosing Party’s Confidential Information to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

(a) in order and to the extent required to comply with applicable Law (including any securities Law or regulation or the rules of a securities exchange) or with a legal, regulatory or administrative proceeding;

(b) in connection with prosecuting or defending litigation, and filing, prosecuting and enforcing LNP Technology Patents in connection with Receiving Party’s rights and obligations pursuant to this License Agreement; and

(c) to acquirers or permitted assignees; investment bankers, investors and lenders, including potential acquirers, assignees, investment bankers, and lenders;

(d) in the case of BioNTech, to (i) subcontractors; or (ii) potential licensees or collaboration partners, but in case (ii) only such information that is reasonably necessary or useful for the potential licensee or partner to evaluate the applicable Licensed Product, and LNP/Licensed Product manufacturing processes, but excluding the particular chemical structure and formulation of any LNPs (which excluded information may be disclosed to such potential licensee or partner upon Acuitas’ prior written consent);

provided that (1) where reasonably possible, Receiving Party will notify Disclosing Party of Receiving Party’s intent to make any disclosure pursuant to subsections (a) and (b) sufficiently prior to making such disclosure so as to allow Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed, and (2) with respect to subsections (c) and (d), each of those entities are required to comply with the restrictions on use and disclosure in Section 8.2 (other than investment bankers, investors and lenders, which must be bound prior to disclosure by commercially reasonable obligations of confidentiality).

8.5 Return of Confidential Information. Upon expiry or earlier termination of this License Agreement, upon written request of a Party (such request, if made, to be made within [***] months of such expiry or termination) the other Party will destroy or return (as shall be specified in such request) to the requesting Party all copies of the Confidential Information of the requesting Party; provided that the Party may retain: (i) one copy of such Confidential Information for record-keeping purposes, for the sole purpose of ensuring compliance with this Agreement; (ii) any copies of such Confidential Information as is required to be retained under applicable Law; (iii) any copies of such Confidential Information as is necessary or useful for such Party to exercise a right or fulfill an obligation under another License Agreement, if any, or as set forth in this License Agreement; and (iv) any copies of any computer records and files containing Confidential Information that have been created by such Party’s routine archiving/backup procedures.
8.6 Publications. Notwithstanding anything in this License Agreement to the contrary, BioNTech is permitted to publish the results of its development under this License Agreement, provided, however, that it will not disclose Acuitas Confidential Information in any publication by BioNTech of the results of any Licensed Product development by BioNTech without Acuitas’ prior written consent, which will not be unreasonably withheld, conditioned or delayed.

8.7 Terms of this License Agreement; Publicity. The Parties agree that the existence and terms of the Parties’ relationship and this License Agreement will be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Section 8.4. Except as required by Law, each Party agrees not to issue any press release or public statement disclosing information relating to the existence of this License Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Party.

9. Warranties; Limitations of Liability; Indemnification.

9.1 Representations and Warranties. Each Party represents and warrants to the other as of the License Agreement Effective Date that:

(a) it is a corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated,

(b) it has the legal right and power to enter into this License Agreement, to extend the rights and licenses granted or to be granted to the other in this License Agreement, and to fully perform its obligations hereunder,

(c) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this License Agreement and the performance of its obligations hereunder and

(d) this License Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

9.2 Additional Representations of Acuitas. Except as set forth on Appendix 9.2, Acuitas hereby represents and warrants to BioNTech as of the License Agreement Effective Date as follows:

(a) Impairment. Neither Acuitas nor any of its Affiliates has entered into any agreement or otherwise licensed, granted, assigned, transferred, conveyed or otherwise encumbered or disposed of any right, title or interest in or to any of its assets, including any intellectual property rights including Know-How, that would in any way conflict with or impair the scope of any rights or licenses granted to BioNTech hereunder, including under any of the agreements which Acuitas has identified to BioNTech prior to the License Agreement Effective Date.

(b) Patents. Appendix 1.1 sets forth a complete and accurate list of all LNP Technology Patents. Acuitas Controls, and will Control during the Term, the LNP Technology Patents listed on Appendix 1.1 and the Know-How within the Acuitas LNP Technology, and is entitled to grant the licenses specified herein. To Acuitas’ knowledge, the LNP Technology Patents have been procured or are being procured from the respective patent offices in accordance with applicable Law. None of the LNP Technology Patents is or has been involved in any opposition, cancellation, interference, reissue or reexamination proceeding, and to Acuitas’ knowledge as of the License Agreement Effective Date, no Acuitas LNP Technology is the subject of any judicial, administrative or arbitral order, award, decree, injunction, lawsuit, proceeding or stipulation. Neither Acuitas nor any of its Affiliates has received any notice alleging that the LNP Technology Patents are invalid or unenforceable, or challenging Acuitas’ ownership of or right to use any such rights before the Effective Date.
Entire LNP Technology. The Acuitas LNP Technology licensed to BioNTech under this License Agreement comprises all Technology Controlled by Acuitas which is required to develop, manufacture and commercialize the Licensed Products.

Encumbrances. Acuitas and its Affiliates are not subject to any payment obligations to Third Parties as a result of the execution or performance of this License Agreement. Until the License Agreement Effective Date, neither Acuitas nor any of its Affiliates has granted any license or security interests on the Acuitas LNP Technology, and the Acuitas LNP Technology as licensed hereby is free and clear of any mortgage, pledge, claim, security interest, covenant, easement, encumbrance, lien or charge of any kind.

Defaults. The execution, delivery and performance by Acuitas of this License Agreement and the consummation of the transactions contemplated hereby will not result in any violation of, conflict with, result in a breach of or constitute a default under any understanding, contract or agreement to which Acuitas is a party or by which it is bound, including each of the agreements which Acuitas has identified to BioNTech prior to the License Agreement Effective Date, in each case as would reasonably be expected to have a material adverse effect on the rights granted to BioNTech hereunder.

Litigation. There is no action, suit, proceeding or investigation pending or, to the knowledge of Acuitas, currently threatened in writing against or affecting Acuitas that questions the validity of this License Agreement or the right of Acuitas to enter into this License Agreement or consummate the transactions contemplated hereby or that relates to the Acuitas LNP Technology.

Infringement. Neither Acuitas nor any of its Affiliates has received any notice of any claim, nor does Acuitas or its Affiliates have any knowledge of any basis for any claim, that any Patent, Know-How or other intellectual property owned or controlled by a Third Party would be infringed or misappropriated by the practice of any Acuitas LNP Technology in connection with the production, use, research, development, manufacture or commercialization of any Licensed Product.

To Acuitas’ knowledge, no Third Party is infringing or has infringed any Patent within the Acuitas LNP Technology or is misappropriating or has misappropriated any Know-how within the Acuitas LNP Technology.

Disclaimers. Without limiting the respective rights and obligations of the Parties expressly set forth herein, each Party specifically disclaims any guarantee that any Licensed Product will be successful, in whole or in part. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS LICENSE AGREEMENT, THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTY OF ANY KIND UNDER THIS LICENSE AGREEMENT, EITHER EXPRESS OR IMPLIED.

No Consequential Damages. NOTWITHSTANDING ANYTHING IN THIS LICENSE AGREEMENT OR OTHERWISE, NEITHER PARTY WILL BE LIABLE TO THE OTHER OR ANY THIRD PARTY WITH RESPECT TO ANY SUBJECT MATTER OF THIS LICENSE AGREEMENT FOR ANY INDIRECT, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES; PROVIDED THAT THIS SECTION 9.4 WILL NOT APPLY TO BREACHES OF A PARTY’S OBLIGATIONS OR UNDER ARTICLE NINE OR THE PARTIES’ INDEMNIFICATION RIGHTS AND OBLIGATIONS UNDER SECTION 9.6.
9.6 Indemnification.

(a) Indemnification by BioNTech. BioNTech will indemnify Acuitas, its Affiliates and their respective directors, officers, employees, Third Party licensors and agents, and their respective successors, heirs and assigns (collectively, “Acuitas Indemnitees”), and defend and hold each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys’ fees and expenses) (collectively, “Losses”) in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, “Third Party Claims”) against the Acuitas Indemnitees to the extent arising from or occurring as a result of: (i) the breach by BioNTech of any provision of this License Agreement; (ii) any negligence or willful misconduct on the part of any BioNTech Indemnitee; or (iii) the development or commercialization by or on behalf of BioNTech or any of its Affiliates or Sublicensees of Licensed Product other than if related to an LNP component thereof, except in each case (i)-(iii) to the extent arising from or occurring as a result of the negligence or willful misconduct on the part of an Acuitas Indemnitee or Acuitas’ breach of this License Agreement.

(b) Indemnification by Acuitas. Acuitas will indemnify BioNTech, its Affiliates and their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, “BioNTech Indemnitees”), and defend and hold each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims against BioNTech Indemnitees to the extent arising from or occurring as a result of: (i) the breach by Acuitas of any provision of this License Agreement; or (ii) any negligence or willful misconduct on the part of any Acuitas Indemnitee, or (iii) [***].

(c) Notice of Claim. All indemnification claims provided for in Sections 9.6(a) and 9.6(b) will be made solely by such Party to this License Agreement (the “Indemnified Party”). The Indemnified Party will promptly notify the indemnifying Party (an “Indemnification Claim Notice”) of any Losses or the discovery of any fact upon which the Indemnified Party intends to base a request for indemnification under Section 9.6(a) and 9.6(b), but in no event will the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and estimated amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party will furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

(d) Defense, Settlement, Cooperation and Expenses.

(i) Control of Defense. At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [***] days after the indemnifying Party’s receipt of an Indemnification Claim Notice. The assumption of the defense of the Indemnified Party in respect of the Third Party Claim, nor will it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party’s claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the...
Third Party Claim any legal counsel selected by the indemnifying Party (the indemnifying Party will consult with the Indemnified Party with respect to such counsel and a possible conflict of interest of such counsel retained by the indemnifying Party). In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party will immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party will reimburse the indemnifying Party for any and all costs and expenses (including reasonable attorneys’ fees and costs of suit) and any Third Party Claims incurred by the indemnifying Party in its defense of the Third Party Claim.

(ii) Right to Participate in Defense. Without limiting Section 9.6(d)(i), any Indemnified Party will be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment will be at the Indemnified Party’s own cost and expense unless (i) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 9.6(d)(i) (in which case the Indemnified Party will control the defense) or (ii) the interests of the Indemnified Party and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under applicable Law, ethical rules or equitable principles, in which case the indemnifying Party will assume one hundred percent (100%) of any such costs and expenses of counsel for the Indemnified Party.

(iii) Settlement. With respect to any Third Party Claims that relate solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnified Party’s becoming subject to injunctive or other relief or otherwise adversely affecting the business of the Indemnified Party in any manner, and as to which the indemnifying Party will have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party will have the sole right to agree to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, will deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 9.6(d)(i), the indemnifying Party will have authority to agree to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss provided it obtains the prior written consent of the Indemnified Party (such consent not to be unreasonably withheld, delayed or conditioned). The indemnifying Party will not be liable for any settlement or other disposition of a Loss by an Indemnified Party that is reached without the prior written consent of the indemnifying Party. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party will admit any liability with respect to or settle, compromise or discharge, any Third Party Claim without the prior written consent of the indemnifying Party, such consent not to be unreasonably withheld, delayed or conditioned.

(iv) Cooperation. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party will, and will cause each other indemnified party to, cooperate in the defense or prosecution thereof and will furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith, at the indemnifying Party’s expense. Such cooperation will include access during normal business hours afforded to the indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making indemnified parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party will reimburse the Indemnified Party for all its reasonable out-of-pocket costs and expenses in connection therewith.
(v) Costs and Expenses. Except as provided above in this Section 9.6(d), the costs and expenses, including attorneys’ fees and expenses, incurred by the Indemnified Party in connection with any claim will be reimbursed on a Calendar Quarter basis by the indemnifying Party, without prejudice to the indemnifying Party’s right to contest the Indemnified Party’s right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

9.7 Insurance. Each Party will maintain at its sole cost and expense, an adequate liability insurance or self-insurance program (including product liability insurance) to protect against potential liabilities and risk arising out of activities to be performed under this License Agreement, and any agreement related hereto and upon such terms (including coverages, deductible limits and self-insured retentions) as are customary in the respective industry of such Party for the activities to be conducted by such Party under this License Agreement. Subject to the preceding sentence, such liability insurance or self-insurance program will insure against all types of liability, including personal injury, physical injury or property damage arising out of the manufacture, sale, use, distribution or marketing of Licensed Product. The coverage limits set forth herein will not create any limitation on a Party’s liability to the other under this License Agreement.

10. Term and Termination.

10.1 Term. This License Agreement will commence as of the License Agreement Effective Date and, unless sooner terminated in accordance with the terms hereof or by mutual written consent, will continue on a Licensed Product-by-Licensed Product and a country-by-country basis, until there are no more payments owed to Acuitas in such country (the longest such period of time hereunder, the “Term”). Upon there being no more such payments hereunder in such country, the license contained in Section 2.1 will become fully paid up and will remain in effect with respect to such Licensed Product in such country.

10.2 Termination by Acuitas.

(a) Breach. Acuitas will have the right to terminate this License Agreement in full upon delivery of written notice to BioNTech in the event of any material breach by BioNTech of any terms and conditions of this License Agreement, provided that such breach has not been cured within [***] days after written notice thereof is given by Acuitas to BioNTech specifying the nature of the alleged breach.

(b) Disputed Breach. If BioNTech disputes in good faith the existence or materiality of a breach specified in a notice provided in accordance with Section 10.2(a), and BioNTech provides Acuitas notice of such dispute within such [***]-day period, then Acuitas shall not have the right to terminate this License Agreement under Section 10.2(a) unless and until it is finally determined, in accordance with Section 11.1, that BioNTech has materially breached this License Agreement and that BioNTech fails to cure such breach within [***] days following such decision. It is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this License Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder. During the pendency of any such dispute, BioNTech shall pay to Acuitas all Acuitas Milestone payments and royalty payments set forth herein.

23
10.3 Termination by BioNTech.

(a) **Breach.** BioNTech will have the right to terminate this License Agreement in full upon delivery of written notice to Acuitas in the event of any material breach by Acuitas of any terms and conditions of this License Agreement, provided that such breach has not been cured within [***] days after written notice thereof is given by BioNTech to Acuitas specifying the nature of the alleged breach.

(b) **Discretionary Termination.** BioNTech will have the right (i) to terminate this License Agreement in full at its discretion for any reason by delivering written notice to Acuitas, such termination to be effective [***] days following the date of such notice.

(c) **Alternative to Termination Under Section 10.3(a).** If BioNTech has the right to terminate this License Agreement under Section 10.3(a) as a result of a material breach by Acuitas (including following expiration of all applicable cure periods thereunder) that fundamentally impairs the value of BioNTech’s rights hereunder with respect to the Licensed Target, then BioNTech may, in lieu of exercising such termination right, elect by written notice to Acuitas before the end of such applicable cure period to have this License Agreement continue in full force and effect for the Term, provided that the following will apply: [***].

10.4 Termination Upon Bankruptcy. All rights and licenses granted under or pursuant to this License Agreement by Acuitas are, and will otherwise be deemed to be, for purposes of Section 65.11(7) of the Bankruptcy and Insolvency Act, R.S.C. 1985, c. B-3 and Section 32(6) of the Companies’ Creditors Arrangement Act, R.S.C. 1985, c. C-36 (the “Insolvency Legislation”), a grant of “right to use intellectual property” as used in the Insolvency Legislation. The Parties agree that BioNTech and its Affiliates and Sublicensees, as licensees of such rights under this License Agreement, will retain and may fully exercise all of their rights and elections under the Insolvency Legislation subject to the payment of amounts provided for herein. Without limiting BioNTech’s rights under the Insolvency Legislation, if Acuitas becomes insolvent or makes an assignment for the benefit of its creditors or there is filed by or against the Acuitas any bankruptcy, receivership, reorganization or similar proceeding (an “Insolvency Event”) pursuant to or under the Insolvency Legislation or otherwise, BioNTech shall be entitled to a copy of any and all such intellectual property and all embodiments of such intellectual property, and the same, if not in the possession of Acuitas, shall be promptly delivered to it (i) before this License Agreement is rejected by or on behalf of Acuitas, within [***] days after BioNTech’s written request, unless Acuitas, or its trustee or receiver, elects within [***] days to continue to perform all of its obligations under this License Agreement, or (ii) after any rejection of this License Agreement by or on behalf of Acuitas, if not previously delivered as provided under clause (i) above. All rights of the Parties under this Section 10.4(b) and under Section 65.11(7) of the Bankruptcy and Insolvency Act, R.S.C. 1985, c. B-3 and Section 32(6) of the Companies’ Creditors Arrangement Act are in addition to and not in substitution of any and all other rights, powers, and remedies that each party may have under this License Agreement, the Insolvency Legislation, and any other applicable Laws. BioNTech shall have the right to perform the obligations of Acuitas hereunder with respect to such intellectual property, but neither such provision nor such performance by BioNTech shall release Acuitas from any such obligation or liability for failing to perform it.
10.5 Effects of Termination. Upon termination (but not expiration pursuant to Section 10.1) of this License Agreement for any reason:

(a) Cessation of Rights. Except as otherwise expressly provided herein, including in Sections 8.5, 10.3(c) and 10.5(b), all rights and licenses granted by Acuitas to BioNTech in Section 2.1 will terminate.

(b) Sell Off. Notwithstanding the termination of BioNTech's licenses and other rights under this License Agreement, BioNTech shall retain the right to distribute, sell or otherwise dispose of its existing inventory of the Licensed Products, in each case that is intended for distribution, sale or disposition in the Territory, for a period of not more than [***] months following the date of the effective termination, as though this License Agreement had not been terminated, and such distribution, sale or other disposition shall not constitute infringement of the Patents or other intellectual property or proprietary rights of Acuitas or its Affiliates. BioNTech's right to distribute, sell or otherwise dispose of its existing inventory of the Licensed Products pursuant to this Section 10.5(b) shall be subject to BioNTech's continuing obligation to pay royalties with respect to the Net Sales.

10.6 Survival. In addition to the termination consequences set forth in Section 10.5, the following provisions will survive termination or expiration of this License Agreement: Articles 1 and 8 and Sections 4.4, 5.1, 9.3, 9.4, 9.6, 9.7, 10.4, 10.5, 10.6, 11.1, 11.2, 11.5, 11.7, 11.8, 11.9, 11.10, 11.11 and 11.12. Termination or expiration of this License Agreement will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration 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 License Agreement nor prejudice either Party's right to obtain performance of any obligation. All other rights and obligations will terminate upon expiration of this License Agreement.


11.1 Dispute Resolution

(a) Disputes. Disputes arising under or in connection with this License Agreement will be resolved pursuant to this Section 11.1; provided, however, that in the event a dispute cannot be resolved without an adjudication of the rights or obligations of a Third Party (other than any BioNTech Indemnitees or Acuitas Indemnitees identified in Section 9.6), the dispute procedures set forth Sections 11.1(c) and 11.1(e) will be inapplicable as to such dispute.

(b) Dispute Escalation. In the event of a dispute between the Parties, the Parties will first attempt in good faith to resolve such dispute by negotiation and consultation between themselves. In the event that such dispute is not resolved on an informal basis within [***] days, any Party may, by written notice to the other, have such dispute referred to each Party's [***], who will attempt in good faith to resolve such dispute by negotiation and consultation for a [***] day period following receipt of such written notice
(c) **Dispute Resolution.** In the event the [***] of the Parties are not able to resolve such dispute as set forth above, the Parties agree to try to solve such dispute amicably by mediation. The Parties shall conduct a mediation procedure according to the Mediation Rules of the World Intellectual Property Organization (WIPO) in effect on the date of the commencement of the mediation proceedings. The location of the mediation proceedings will be London, England. The number of mediators will be [***]. The language of the mediation proceedings will be English. If the dispute has not been settled pursuant to the said rules within [***] days following the filing of a request for mediation or within such other period as the Parties may agree in writing, either Party may submit the dispute to final and binding arbitration. Any dispute relating to the validity, performance, construction or interpretation of this Agreement, which cannot be resolved amicably between the Parties after following the procedure set forth in this Section 11.1, shall be submitted to arbitration in accordance with the Arbitration Rules of WIPO in effect on the date of the commencement of the arbitration proceedings. The location of the arbitration proceedings will be London, England. The number of arbitrators will be [***]. The language of the arbitration proceeding will be English. The decision of the arbitrators shall be final and binding upon the Parties (absent manifest error on the part of the arbitrator(s)) and enforceable in any court of competent jurisdiction.

(d) **Injunctive Relief.** Notwithstanding the dispute resolution procedures set forth in this Section 11.1, in the event of an actual or threatened breach hereunder, the aggrieved Party may seek equitable relief (including restraining orders, specific performance or other injunctive relief) in any court or other forum, without first submitting to any dispute resolution procedures hereunder.

(e) **Tolling.** The Parties agree that all applicable statutes of limitation and time-based defenses (such as estoppel and laches) will be tolled while the dispute resolution procedures set forth in this Section 11.1 are pending, and the Parties will cooperate in taking all actions reasonably necessary to achieve such a result.

(f) **Prevailing Party.** The prevailing Party in any arbitration under Section 11.1(c) or any other suit related to this License Agreement will be entitled to recover from the losing Party all out-of-pocket fees, costs and expenses (including those of attorneys, professionals and accountants and all those arising from appeals and investigations) incurred by the prevailing Party in connection with such arbitration or suit.

11.2 **Cumulative Remedies and Irreparable Harm.** All rights and remedies of the Parties hereunder will be cumulative and in addition to all other rights and remedies provided hereunder or available by agreement, at Law or otherwise. Each Party acknowledges and agrees that breach of any of the terms or conditions of this License Agreement may cause irreparable harm and damage to the other and that such damage may not be ascertainable in money damages and that as a result thereof the non-breaching Party may be entitled to seek from a court equitable or injunctive relief restraining any breach or future violation of the terms contained herein by the breaching Party without the necessity of proving actual damages or posting bond. Such right to equitable relief is in addition to whatever remedies either Party may be entitled to as a matter of Law or equity, including money damages.

11.3 **Relationship of Parties.** Nothing in this License Agreement is intended or will be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party will incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided therein. There are no express or implied third party beneficiaries hereunder (except for BioNTech Indemnitees and Acuitas Indemnitees for purposes of Section 9.6). For clarity, BioNTech does not grant to Acuitas any rights or licenses under this License Agreement to any BioNTech technology or intellectual property rights.

11.4 **Compliance with Law.** Each Party will perform or cause to be performed any and all of its obligations or the exercise of any and all of its rights hereunder in good scientific manner and in compliance with all applicable Law.
11.5 **Governing Law.** This License Agreement will be governed by and construed in accordance with the Laws of England and Wales, without respect to its conflict of Laws rules, provided that any dispute relating to the scope, validity, enforceability or infringement of any Patents or Know-How will be governed by, and construed and enforced in accordance with, the substantive Laws of the jurisdiction in which such Patents or Know-How apply.

11.6 **Counterparts; Facsimiles.** This License Agreement may be executed in one or more counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. Facsimile or PDF execution and delivery of this License Agreement by either Party will constitute a legal, valid and binding execution and delivery of this License Agreement by such Party.

11.7 **Headings.** All headings in this License Agreement are for convenience only and will not affect the meaning of any provision hereof.

11.8 **Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this License Agreement. Accordingly, the rule of construction that any ambiguity in this License Agreement will be construed against the drafting party will not apply.

11.9 **Interpretation.** Whenever any provision of this License Agreement uses the term “including” (or “includes”), such term will be deemed to mean “including without limitation” (or “includes without limitations”). “Herein,” “hereby,” “hereunder,” “hereof” and other equivalent words refer to this License Agreement as an entirety and not solely to the particular portion of this License Agreement in which any such word is used. All definitions set forth herein will be deemed applicable whether the words defined are used herein in the singular or the plural. Unless otherwise provided, all references to Sections and Appendices in this License Agreement are to Sections and Appendices of this License Agreement. References to any Sections include Sections and subsections that are part of the related Section.

11.10 **Binding Effect.** This License Agreement will inure to the benefit of and be binding upon the Parties, their Affiliates, and their respective lawful successors and assigns.

11.11 **Assignment.** This License Agreement may not be assigned by either Party, nor may either Party delegate its obligations or otherwise transfer licenses or other rights created by this License Agreement, except as expressly permitted hereunder or otherwise without the prior written consent of the other Party, which consent will not be unreasonably withheld; provided that either Party may assign this License Agreement without such consent to an Affiliate or to its successor in connection with sale of all or substantially all of its assets or business or that portion of its business pertaining to the subject matter of this License Agreement (whether by merger, consolidation or otherwise).

11.12 **Notices.** All notices, requests, demands and other communications required or permitted to be given pursuant to this License Agreement will be in writing and will be deemed to have been duly given upon the date of receipt if delivered by hand, recognized international overnight courier, or registered or certified mail, return receipt requested, postage prepaid to the following addresses:

If to BioNTech:
BioNTech SE An der Goldgrube 12
D-5513 Mainz
Germany
Attention: [***]
Either Party may change its designated address by notice to the other Party in the manner provided in this Section 11.12.

11.13 Amendment and Waiver. This License Agreement may be amended, supplemented, or otherwise modified only by means of a written instrument signed by both Parties; provided that any unilateral undertaking or waiver made by one Party in favor of the other will be enforceable if undertaken in a writing signed by the Party to be charged with the undertaking or waiver. Any waiver of any rights or failure to act in a specific instance will relate only to such instance and will not be construed as an agreement to waive any rights or fail to act in any other instance, whether or not similar.

11.14 Severability. In the event that any provision of this License Agreement will, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability will not affect any other provision hereof, and the Parties will negotiate in good faith to modify the License Agreement to preserve (to the extent possible) their original intent.

11.15 Entire Agreement. This License Agreement together with the Development and Option Agreement and any other license agreements entered into during the Term pursuant to the Development and Option Agreement are the sole agreement with respect to the subject matter hereof and supersede all other agreements and understandings between the Parties with respect to same.

11.16 Force Majeure. Neither Acuitas nor BioNTech will be liable for failure of or delay in performing obligations set forth in this License Agreement (other than any obligation to pay monies when due), and neither will be deemed in breach of such obligations, if such failure or delay is due to natural disasters or any causes reasonably beyond the control of Acuitas or BioNTech, provided that the Party affected will promptly notify the other of the force majeure condition and will exert reasonable efforts to eliminate, cure or overcome any such causes and to resume performance of its obligations as soon as possible.
WITNESS WHEREOF, the Parties have caused this License Agreement to be executed by their respective duly authorized officers as of the License Agreement Effective Date.

ACUTAS THERAPEUTICS INC.

By: __________________________________________
   (Signature)

Name: Thomas Madden
Title: President & CEO
Date: April 7, 2020

BIOTECH RNA PHARMACEUTICALS GMBH

By: __________________________________________
   (Signature)

Name: __________________________
Title: __________________________
Date: __________________________

Signature Page to License Agreement
Exceptions to Acuitas’ Representations and Warranties in Section 9.2
SENSITIVE

THE SYMBOL “[***]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

PURCHASE AGREEMENT ("PA") for the further development, production, purchasing options and supply of COVID-19 Vaccines for EU Member States

NUMBER — SANTE/2021/03/020

1. The European Commission, acting on behalf and in the name of the Member States set out in Annex III (hereinafter referred to as “Participating Member States”),

   being represented for the purposes of the signature of this PA by Ms Stella Kyriakides, Commissioner of Health and Food Safety on the one part and

2. Pfizer Inc.

   Incorporated in Delaware (Registration Number 0383418) with its registered address at 235 East 42nd Street

   10017 New York City, NY (UNITED STATES)

   appointed as the leader of the group by the members of the group that submitted the joint tender

   (hereinafter referred to as “Pfizer”)

   and

   BioNTech Manufacturing GmbH

   Registered with the commercial register of the lower court (Amtsgericht) of Mainz, Germany under HRB 47548, with its registered address at An der Goldgrube 12

   55131 MAINZ, GERMANY

   (hereinafter referred to as “BioNTech”)

1 This PA is based on the agreement between the Commission and the Member States as approved by Commission Decision C(2020) 4192 final on approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures.

as a member of the group (collectively "the Contractor"), represented for the purposes of the signature of this PA which has the form of a framework contract by [***]

on the other part,

HAVE AGREED

to the special conditions and the general conditions of this PA and the following Annexes and Attachments:

Annex I – Model for Vaccine Order Form

Annex II – Agreement between the Commission and Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures, annexed to the Commission Decision C(2020) 4192 final of 18 June 2020

Annex III – Participating Member States

Annex IV – Subcontractors

Annex V – Participating Contractor Affiliates

Attachment 1 – Specifications

Attachment 2 – Delivery Documentation

Attachment 3 – Delivery Specification

Attachment 4 – Labelling and Packaging Specifications

Attachment 5 – Return and Disposal of Product Materials

which form an integral part of this PA.

[***]

[***]

[***]

[***]

For any other proposed amendments, the parties will discuss the impact thereof in good faith and any such shall require the written prior approval of the Commission and the Participating Member States, not to be unreasonably withheld or delayed.

2
This PA sets out:

1. the procedure and conditions by which the Participating Member States will pay for the services and/or supplies from the Contractor;
2. the provisions that apply to any Vaccine Order Form which the Participating Member States and the Contractor may conclude under this PA; and
3. the obligations of the parties during and after the duration of this PA.

All documents issued by the Contractor (end-user agreements, general terms and conditions, etc.) except its tender are held inapplicable, unless explicitly mentioned in the special conditions of this PA. In all circumstances, in the event of contradiction between this PA and documents issued by the Contractor, this PA prevails, regardless of any provision to the contrary in the Contractor’s documents.
TABLE OF CONTENT

I. SPECIAL CONDITIONS
   1.1 Order of Priority of Provisions
   1.2 Definitions
   1.3 Subject Matter
   1.4 Entry into force and duration of the PA
   1.5 Implementation of the PA
   1.6 Supply of the Vaccine
   1.7 Prices
   1.8 Payment Arrangements
   1.9 Communication Details
   1.10 Project management
   1.11 Exploitation of the results of the PA
   1.12 Indemnification
   1.13 Applicable Law and Settlement of Disputes
   1.14 Other Special Conditions

II. GENERAL CONDITIONS FOR THE FRAMEWORK CONTRACT FOR SERVICES
   2.1 Definitions
   2.2 Roles and responsibilities in the event of a joint tender
   2.3 Severability
   2.4 Provision of services and supplies
   2.5 Communication between the parties
   2.6 Liability
   2.7 Conflict of interest and professional conflicting interests
   2.8 Representations and warranties
   2.9 Confidentiality
   2.10 Announcements and publicity
   2.11 Processing of personal data
   2.12 Subcontracting
   2.13 Amendments
   2.14 Assignment
   2.15 Force majeure
   2.16 Suspension of the implementation of the PA
   2.17 Termination of the PA
   2.18 Invoices, value added tax and e-invoicing
1. SPECIAL CONDITIONS

1.1 ORDER OF PRIORITY OF PROVISIONS

If there is any conflict between different provisions in this PA, the following rules must be applied:

(a) The provisions set out in the special conditions and Article II.6 of the general conditions (Liability) take precedence over those in the other parts of the PA.
(b) The other provisions set out in the general conditions take precedence over those in the Annexes and Attachments.
(c) The provisions set out in the PA take precedence over those in the Vaccine Order Forms.

1.2 DEFINITIONS

The following definitions shall apply to this PA:

‘Additional Order’: has the meaning set forth in Article I.6.2;

‘Additional Product’: has the meaning set forth in Article I.6.2;

‘Affiliate’: means in relation to a body corporate, any other entity which directly or indirectly Controls, is Controlled by, or is under direct or indirect common Control of that body corporate from time to time;

‘Authorisation’: means a Conditional Marketing Authorisation and/or Marketing Authorisation that permits the Products to be placed on the market in the European Economic Area;

‘Commission Experts’ means up to three (3) clinical expert individuals employed by, or advising, the Commission in connection with the COVID-19 pandemic, such individuals to be identified by the Commission and communicated to Contractor promptly following the Effective Date (it being understood that if Contractor expresses a reasonable objection to the identity of one or more Commission Experts, the Commission will suggest (an) alternative expert(s));

‘Conditional Marketing Authorisation’: means a conditional marketing authorisation granted by the European Commission, as amended or varied from time to time, as referred to in Article 14-a of Regulation (EC) No 726/2004;

‘Confidential Information’: means any information disclosed to or obtained by one party to the other party, either directly or indirectly, or which the disclosing party indicates in writing at the time of disclosure to, or receipt by, the recipient is to be considered confidential or proprietary, or which such recipient knows or ought reasonably to know is information of a
confidential or proprietary nature, including the terms of this PA and any Vaccine Order Form. Confidential Information shall not include any information (i) the receiving party can prove was known to it prior to the date of disclosure; (ii) the receiving party can prove was lawfully obtained from a third party without any obligation of confidentiality; (iii) is or becomes part of the public domain other than through any act or omission of the receiving party; or (iv) is independently developed by the receiving party without use of or reference to the disclosing party’s Confidential Information, as evidenced by the receiving party’s records;

‘Conflict of interest’: a situation where the impartial and objective implementation of the PA by the Contractor is compromised for reasons involving family, emotional life, political or national affinity, economic interest, any other direct or indirect personal interest, or any other shared interest with the Commission, the Participating Member State or any third party related to the subject matter of the PA;

‘Contracted Doses’: has the meaning set forth in Article I.6.2;

‘Control’: means the possession by a person or an entity, directly or indirectly, of the power to direct or cause the direction of the management and policies of the other person or entity (whether through the ownership of voting shares, by contract or otherwise) and “Controls” and “Controlled” shall be interpreted accordingly;

“COVAX Facility” means the COVID-19 Vaccines Global Access procurement initiative led by Gavi, UNICEF, the Vaccine Alliance, the World Health Organization (WHO) and the Coalition for Epidemic Preparedness Innovations (CEPI), for the procurement and delivery of doses of approved vaccine for COVID-19;

‘Delivery Price’: has the meaning set forth in Article I.8.2;

‘Delivery Schedule’: has the meaning set forth in Article I.6.3, as such may be modified by agreement of the parties pursuant to the provisions in Articles I.6.2 and I.6.3;

‘Effective Date’: has the meaning set forth in Article I.4.1;

‘Force majeure’: any unforeseeable, exceptional situation or event beyond the reasonable control of the parties that prevents either of them from fulfilling any of their obligations under the PA, [***];

‘Formal notification’ (or ‘formally notify’): form of communication between the parties made in writing by mail or email, which provides the sender with compelling evidence that the message was delivered to the specified recipient;

‘Fraud’: an act or omission committed in order to make an unlawful gain for the perpetrator or another by causing a loss to the Union’s financial interests, and relating to: i) the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the misappropriation or wrongful retention of funds or assets from the Union budget, ii) the non-disclosure of information in violation of a specific obligation, with the same effect or iii)
the misapplication of such funds or assets for purposes other than those for which they were originally granted, which damages the Union’s financial interests, it being understood that the Union’s financial interests are impacted within the framework of this PA as the Union is engaging resources into the coordination and preparation of the PA, resulting from Decision C(2020) 4192 final of 18 June 2020 which approved the agreement with Member States on procuring COVID-19 vaccines on behalf of the Member States (“the Decision”), this agreement being based on Article 4(5)(b) of Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union (“the ESI Regulation”);


‘Implementation of the PA’ the purchase of services or supplies envisaged in the PA through the signature and performance of Vaccine Order Forms;

‘Indemnified Persons’ has the meaning set forth in Article 0;

‘Irregularity’ any infringement of a provision of Union law resulting from an act or omission by the Contractor within the meaning of Article 1(2) of the Council (EC, Euratom) Regulation 2988/95 of 18 December 1995 on the protection of the European Communities financial interests (in OJ 23.12.95, L 312/1), which has, or would have, the effect of prejudicing the Union’s budget, it being understood that the Union’s financial interests are impacted within the framework of this PA, as the Union is engaging resources into the coordination and preparation of the PA, resulting from the Decision which approved the agreement with Member States on procuring COVID-19 vaccines on behalf of the Member States, this agreement being based on Article 4(5)(b) of the ESI Regulation;

[***]

‘Key Supply/ies’ means those critical components, services and other critical input items required for the development, production and supply of the Vaccine pursuant to this PA, for which a delay in their supply is capable of materially adversely affecting the timely performance of the Contractor’s delivery obligations under this PA.

[***]

[***]

‘Latent Defect’ means a defect causing the Product to not conform to the applicable Specifications which could not have been detected by the Participating Member State, its designee, or their personnel at delivery through visual inspection;

‘Law(s)’: means, collectively, all applicable supranational, national and local laws, common laws, statutes, ordinances, codes, rules, regulations, orders, decrees or other pronouncements of any government, administrative or judicial authority having the effect of law;

‘Losses’: has the meaning set forth in Article 0;

‘Marketing Authorisation’: means the marketing authorisation (other than Conditional Marketing Authorisation), in respect of the Product granted by the European Commission, as amended or varied from time to time, that allows the Product to be placed on the market in the European Economic Area according to applicable Law;

‘New Countries’: has the meaning set forth in Article I.6.3;

‘Non-Complying Product’: has the meaning set forth in Article I.6.14;

‘Non-EU Key Supplies’: means Key Supplies for which, at the time of production of the Vaccine pursuant to this PA, no supplier exists in the European Union that could provide the component, service and other input item from the territory of the EU. [***]

‘Notification’ (or ‘notify’): form of communication between the parties made in writing including by electronic means;

‘Participating Contractor Affiliate’: means an Affiliate of Pfizer or BioNTech as identified in Annex V;

‘PMS Experts’ means, in relation to each Participating Member State, one (1) clinical expert employed by, or advising, each Participating Member State in connection with the COVID-19 pandemic, the identity of such individual to be communicated by the Commission to Contractor promptly following the Effective Date (it being understood that if Contractor expresses a reasonable objection to the identity of a PMS Expert, the relevant Participating Member State will suggest an alternative expert);

[***]‘Product’ means the Vaccine;

‘Product Materials’: means all packaging materials and components needed for delivery of the Product;

‘Professional conflicting interest’: a situation in which the Contractor’s previous or ongoing professional activities affect its capacity to implement the PA or to perform a Vaccine Order Form to an appropriate quality standard;

‘Record’: means books, documents, and other data, of all matters relating to performance of obligations under this PA;
'Related person': any natural or legal person who is a member of the administrative, management or supervisory body of the Contractor, or who has powers of representation, decision or control with regard to the Contractor;

'Specifications': mean the specifications for the manufacture, testing and testing procedures, and supply of the Product as set out in Attachment 1 (Specifications), and as such specifications may be amended, supplemented or otherwise modified by the Contractor and communicated to the Commission;

'Term': means the term of the PA set out in Article I.4.2 of the PA; ‘Third Party Claim’: has the meaning set forth in Article 0.

‘Vaccine’: the medicinal product, being BNT162b2, a nucleoside-modified messenger RNA (mRNA) vaccine that encodes an optimized SARS-CoV-2 full-length spike glycoprotein (S) for which Authorisation has been granted, [***].

‘Vaccine Order Form’ has the meaning set forth in Article I.5.2; and

‘Vaccine IP Rights’ has the meaning set forth in Article I.11; and

Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”, (c) the word “will” shall be construed to have the same meaning and effect as the word “shall”, (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person shall be construed to include the person’s successors and assigns, (f) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this PA in its entirety and not to any particular provision hereof, (g) all references herein to Articles, Annexes or Attachments shall be construed to refer to Articles, Annexes or Attachments of this PA, and references to this PA include all Annexes and Attachments hereto, (h) the word "notice" means notice in writing or by email (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this PA; (i) provisions that require that a party or parties “agree”, “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (including e-mail), (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof.
I.3 SUBJECT MATTER

The subject of the call for tenders SANTE/2021/03/020 is securing the purchase of certain vaccine doses for the Participating Member States.

Following the Decision, taken in accordance with Article 4(5)(b) of the ESI Regulation, the Commission is running procurement procedures on behalf of Participating Member States, with a view to signing EU-level Advance Purchase Agreements and Purchase Agreements with vaccine manufacturers.

An APA between the Parties was signed on 20 November 2020 (“APA”). Subsequently, a PA between the Parties was signed on 17 February 2021 (“PA.1”).

In compliance with Article 164(1)(d) as well as Annex I, Points 11.1(b)(ii) and 11.1(c) of the Financial Regulation, the Commission launched on 9 April 2021 a negotiated procedure without prior publication of a contract notice for the procurement of additional doses of vaccines. This procedure was justified by the need to urgently secure an exceptionally high amount of additional doses of vaccines to address the pandemic within a reasonable period of time, as well as by the absence of competition for technical reasons. This PA is for such additional doses, and while it is organised following the Decision, it is entirely separate from the APA and from the PA.1 between the Parties.

In view of its importance, this PA will be approved for signature on behalf and in the name of the Participating Member States by a separate individual Commission decision.

The Conditional Marketing Authorisation for the Vaccine was granted on 21 December 2020.

The Commission, on behalf of the Participating Member States, wishes to purchase the Vaccine through this PA to ensure the availability in the European Union of sufficient vaccine doses to address the pandemic[***]

On the basis of this PA, the European Commission commissions the Contractor to commit to produce and deliver 900 million doses of the Vaccine which shall be ordered by the Participating Member States (via specific Vaccine Order Forms) at the price and conditions, including timeframe, agreed under this PA, with the option to obtain a further 900 million doses of the Vaccine subject to the conditions set out in this PA.

The Contractor or a Participating Contractor Affiliate shall supply to the Participating Member States the agreed doses of the Vaccine pursuant to the Vaccine Order Forms.

The Vaccine Order Forms shall be signed by the Contractor and shall incorporate by reference this PA.

I.4 ENTRY INTO FORCE AND DURATION OF THE PA

1.4.1 The PA enters into force on the date on which the last party signs it (“Effective Date”).

1.4.2 The PA is concluded for a period of thirty six (36) months with effect from the Effective Date (“Term”).

1.4.3 Contractor and the Participating Member States may not sign any Vaccine Order Form after the PA expires.

1.4.4 The PA continues to apply to such Vaccine Order Forms after its expiry. [***].

11
1.4.5 Renewal of the PA

The PA will expire automatically at the end of the Term, unless it is extended in mutual written agreement between the parties. For the avoidance of doubt, if the exercise of the Additional Order involves delivery of doses beyond the Term, the parties shall agree to a renewal until the end of the last month for which deliveries of the Additional Order are foreseen in the relevant delivery schedule. This renewal process will be repeated until all doses have been delivered. Renewal does not change or postpone any existing obligations.

1.5 IMPLEMENTATION OF THE PA

1.5.1 Period of provision of the supplies

The period for the provision of the supplies starts to run as foreseen in Article I.6.3.

1.5.2 Implementation of the PA

The PA shall be implemented following signature between the Commission and the Contractor as follows:

The Contractor agrees to supply an initial total number of 900 million Vaccine doses to Participating Member States collectively, upon their order, in accordance with this PA and the respective Vaccine Order Forms.

The Participating Member States shall place orders for supplies of 900 million Vaccine doses in total in accordance with the allocation communicated by the Commission to the Contractor pursuant to Article I.6.3, by sending the Contractor a completed copy of Annex I ("Vaccine Order Form") in paper format or emailed pdf (**). This Vaccine Order Form shall be signed by an authorised representative of the Participating Member State and the Contractor.

(**) the Contractor must send back to the Participating Member States the duly signed and dated Vaccine Order Form in paper format or emailed pdf.

1.6 SUPPLY OF THE VACCINE

1.6.1 General

During the term of this PA, the Contractor shall supply or have supplied the Product to the relevant Participating Member States, and the Participating Member States shall purchase the Product, subject to and in accordance with the terms and conditions of this PA.

1.6.2 Product supply

At the Effective Date, the Commission orders 900 million doses ("Contracted Doses") of the Product on behalf of the Participating Member States. The Contracted Doses shall be delivered by the Contractor to the Participating Member States in accordance with the allocation provided by the Commission and according to the schedule and in the quantities (***) as set out in the Delivery Schedule.
The Additional Order

The parties acknowledge that the Commission may wish to place an additional binding order (the “Additional Order”) for a maximum of up to 900 million doses of the Vaccine, to be exercised (unless otherwise agreed by the parties) in minimum tranches of [***]). Vaccine to be supplied pursuant to an Additional Order will be “Additional Product” [***].

The parties also agree that such Additional Order may be placed by the Commission only after (i) the Contractor confirms whether the doses are available if the request is for more than the minimum Additional Order volume of [***]) and when they can be delivered (ii) the Commission confirms the required allocation between Participating Member States and (iii) the Contractor confirms the delivery schedule which shall be based on the allocation provided (and which shall not commence earlier than [***] ).

All Additional Orders must be placed by the Commission by [***].

The Participating Member States participating in one or more tranches of the Additional Order shall be obliged to send an additional Vaccine Order Form for each tranche of the Additional Order in which they participate. All terms and conditions included in this PA, in particular those included in Article I.6.3 with regard to Deliveries, [***], shall apply mutatis mutandis to the Additional Order.

The Commission shall communicate to the Contractor the allocation of the Contracted Doses supplied pursuant to the initial order and any Additional Product among the Participating Member States.

Resale and Donation

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

I.6.3 Supply mechanism

The supply under this PA shall in principle come from [***], and shall incorporate RNA produced at [***]manufacturing sites, including, [***] sites operated by the following subcontractors:

[***]

[***]

[***]

[***]
The parties acknowledge that Contractor is not obliged to use all these sites provided it has sufficient capacity.

Recognising the urgency of the public health crisis and the necessity to hasten/enable supply, (1) the Commission and Participating Member States shall make best reasonable efforts, where appropriate in collaboration with the European Medicines Agency, to expedite any relevant and outstanding authorisations required for supply to commence from the Contractor’s controlled manufacturing sites [***]. [***]

**Delivery**

The Contracted Doses shall be delivered by the Contractor to the Participating Member States in accordance with the allocation provided by the Commission and according to the schedule and in the quantities [***] as set out in the following table (the “**Delivery Schedule**”):

[***]

[***]

Within [***] following the Effective Date, the Commission shall communicate to the Contractor a table how to allocate the 900 million Vaccine doses amongst the Participating Member States. Each Participating Member State shall have a commitment to purchase the number of Vaccine doses as set out in such allocation table and, to operationalise the ordering of the Vaccine, each Participating Member State will enter into a Vaccine Order Form per Article 1.5.2. Each Vaccine Order Form will specify in particular the number of doses that the Participating Member State will purchase from the above-mentioned allocation table, the price of all Vaccine doses pursuant to Article 1.7, and the liability and indemnification undertakings by the Participating Member State (which will be incorporated by reference from the PA into the Vaccine Order Form). For the avoidance of doubt, the Contractor shall have no obligation to supply any Vaccine doses to any Participating Member State where there is not a Vaccine Order Form, including provisions related to liability and indemnity (which will be incorporated by reference from the PA into the Vaccine Order Form executed by the Participating Member State and the Contractor). It is agreed that the Contractor may discharge its obligations under the Vaccine Order Form acting with one or more Participating Contractor Affiliates.

The Delivery Schedule and logistics will be further refined into a [***] schedule by the Contractor in accordance with provisions below, after the execution of the Vaccine Order Form for that Participating Member State.

To operationalise the Vaccine Order Forms, [***].

For the avoidance of doubt, the Delivery Schedule is firm and no adjustments can be made without the written agreement of the parties. This is without prejudice to the ability of the Contractor to accelerate supply [***].

[***]

[***]

[***]

[***]

---

**14**
I.6.4 Manufacturing

The Contractor warrants that [***].

The Contractor confirms that it is in possession of all necessary manufacturing authorisations to undertake the manufacturing of the Vaccine.

The Contractor also warrants that, [***].

For the purpose of fulfilling its obligation to manufacture the Vaccine, the Contractor shall, in principle, procure all Key Supplies [***].

For each such Key Supply including, in particular, Non-EU Key Supplies, the Contractor commits that it will have in place, when producing the Vaccine doses covered by this PA, an effective supply management system [***].

I.6.5 Legal and regulatory filings and requests

The Contractor shall ensure that all Product is properly labelled and packaged in accordance with the provisions of Article I.6.8 and Good Manufacturing Practice and in accordance with the applicable EU legislation on information on packaging (Title V of Directive 2001/83/EC).

Notwithstanding the above, [***] the Contractor shall comply with all conditions (in the relevant timescales) set out in the Authorisation (where applicable), subject to any exemption, exception or waiver of requirements for the Product granted or permitted by the Participating Member State (including but not limited to serialization).

I.6.6 [***]

I.6.7 Waiver

[***]

I.6.8 Packaging, labelling and shipping

At the date of execution of this PA, the Vaccine is expected to be supplied in a thermal shipping box in accordance with Attachment 4 (Labelling and Packaging Specifications) (“Thermal Shipper”). [***]. The costs of packaging, packing materials, addressing, labelling, loading and delivery to the agreed Participating Member States’ delivery point of the Vaccine [***].

All deliveries shall be accompanied by the documentation specified in Attachment 2 (Delivery Documentation) (which may be updated from time to time by the Contractor upon notice to the Commission), and shall be in accordance with, and subject to, the delivery specification set forth in Attachment 3 (Delivery Specification). The Product shall be labelled and packaged in accordance with the packaging specifications set forth in Attachment 4 (Labelling and Packaging Specifications).
1.6.9 Storage, transport and product acceptance

Final storage specifications, based on the Authorisation received, will be communicated to the Participating Member State prior to delivery.

1.6.10 Delivery

The Contractor will deliver the doses ordered by each of the Participating Member States to one or more locations selected by the Participating Member State in accordance with the procedure set out in this Article 1.6.10 and the Vaccine Order Form. For the avoidance of doubt, the Participating Member States shall bear all costs and expenses for operating these distribution hubs and for use of the Vaccine, including, but not limited to, those for storage and distribution of the Vaccine after delivery, local duties and local QA testing.

The Participating Member States must have all appropriate facilities and personnel in place to enable the timely receipt of delivered doses. The duly authorised representative of the Participating Member State shall sign to confirm receipt of delivery (the current proposed format of which is as set out in Attachment 2 (Delivery Documentation)). The person signing for receipt must ensure the contents of the delivery match the accompanying shipping documentation proof of receipt.

The Contractor shall deliver the Product to the location agreed pursuant to this Article 1.6.10. The Contractor and the Participating Member State shall agree the location(s) for delivery of shipments of the Product, provided that (i) each location meets the requirements set forth in Attachment 3 (Delivery Specification), and (ii) all locations which are additional to those approved in advance by the Contractor prior to the Effective Date shall be agreed upon by the Contractor and the Participating Member State.

All shipments of Product or such other amount as notified to the Commission from time to time by the Contractor in accordance with the terms of this PA.
1.6.11 Product handling

Upon delivery of the Product, the Participating Member State shall store and handle the Product in the manner set forth in the Specifications set forth in Attachment 1 (Specifications), the instructions in Attachment 3 (Delivery Specification) and the instructions provided by the Contractor to ensure stability and integrity of the Product.

The Participating Member States shall be solely responsible and liable for the proper storage, handling, distribution, transportation, administration, use and disposal of the Product in their territories following delivery of the Product to the Participating Member State or its designee. Without prejudice to the generality of the foregoing, the Participating Member States shall ensure that: (a) recipients of the Product shall follow the return and disposal instructions in Attachment 5 (Return and Disposal of Product Materials) when disposing of open and unused Product and its packaging components; and (b) such return and disposal complies with Laws regarding pharmaceutical waste, medical waste, or hazardous waste, as appropriate.

Participating Member States shall be responsible for and shall ensure that any equipment used to deliver the Product, for example are stored in an appropriate clean and secure location to protect and maintain the functionality of such equipment (in controlled conditions, with no exposure to weather or pests, etc). Within of receipt of the Product, subject to Article 1.6.14, the Participating Member State shall take the necessary measures to enable the collection by the Contractor of all such equipment, including in accordance with the Contractor’s instructions, consistent with the provisions of Attachment 5 (Return and Disposal of Product Materials).

The Contractor may provide Safety Data Sheets and other agreed information to Participating Member States.

1.6.12 Title to Product and risk of loss

1.6.13 Quality tests and checks

1.6.14 Rejection of Product; Disposal of rejected shipments

A Participating Member State must visually inspect the Product following the instructions set out in Attachment 3 (Delivery Specification) and may reject any specific delivery of the Product or doses therein that does not conform (“Non-Complying Product”) by providing notice to Pfizer Customer Service following an agreed protocol. Without prejudice to the right to refer the matter to the dispute resolution procedure set out in Article 1.1 and the provision on replacement of Non-Complying Product. The provisions of this Article 1.6.14 shall survive termination or expiration of this PA.

1.6.15 Maintenance and retention of Records

Each party shall maintain with respect to its activities under this PA as required by Laws.
The Participating Member State will maintain a quality system for receipt, inspection, storage, traceability to further delivery points, and recall activities. If the Participating Member State does not have a quality system for the activities defined, the Contractor may share details of a proposed quality system for the Participating Member State's compliance.

1.6.16 Diversion issues
All Product delivered to a Participating Member State shall be: (a) stored securely by the Participating Member State; and (b) without prejudice to Article 1.6.2, distributed by the Participating Member State in a secure manner appropriate to the transportation route and destination, in each case (a) and (b) to guard against and deter theft, diversion, tampering, substitution (with, for example, counterfeits) or unauthorised resale or export out of the Participating Member State, and to protect and preserve the integrity and efficacy of the Product. [***]

1.7 PRICES
The price of the Vaccine to the Commission and the Participating Member States for the 900 million Contracted Doses and any Additional Order will be [***]

1.8 PAYMENT ARRANGEMENTS
1.8.1 [***]
1.8.2 [***] Delivery Price
The Delivery Price for the Contracted Doses and any Additional Order is to be paid by the Participating Member State to the Participating Contractor Affiliate [***]. [***] The Participating Contractor Affiliate may claim the payment of the Delivery Price in accordance with this Article 1.8.2. The Participating Contractor Affiliate must send an invoice in paper format or emailed pdf for payment of the balance due under a Vaccine Order Form for each provision of supplies to the Participating Member States.

Invoices shall be established by the Participating Contractor Affiliate for a given order of supplies and for an identified delivery scheduled within the Vaccine Order Form. The Participating Contractor Affiliate may not send an invoice to a Participating Member State before it receives from the Participating Member State [***] in respect of which such invoice is established, which [***].

The Participating Contractor Affiliate must send an invoice in paper format or emailed pdf or by electronic systems for payment due under the Vaccine Order Form accompanied by the following:
- [***]

Each invoice must contain the following information:
- Name of the Participating Member State concerned
- PA and Vaccine Order Form number/reference
- Order reference
- Billing address
- Product [***]
The Participating Member States must approve the submitted documents or deliverables as conforming to the above requirements and pay [***]. Any payment which falls due on a date which is not a business day may be made on the next succeeding business day. Any dispute by a Participating Member State of an invoice shall be provided to the Participating Contractor Affiliate in writing (along with substantiating documentation and a reasonably detailed description of the dispute) [***]. A Participating Member State will be deemed to have accepted all invoices for which the Participating Contractor Affiliate does not receive timely notification of disputes, and shall pay all undisputed amounts due under such invoices within the period set forth in this Article I.8.2. The parties shall seek to resolve all such disputes expeditiously and in good faith.

In addition to all other remedies available under this PA or at Law, if a Participating Member State fails to pay any undisputed amounts when due under this PA, the Contractor [***].

The Commission and the Participating Member States shall not, and acknowledge that they will have no right, under this PA, any Vaccine Order Form, any order, any other agreement, document or Law, to withhold, offset, recoup or debit any amounts owed (or to become due and owing) to the Participating Contractor Affiliate, against any other amount owed (or to become due and owing) to it by the Contractor or an Affiliate.

I.8.3 Bank account

Payments by the Commission must be made to [***][***][***][***][***][***][***].

1.9 COMMUNICATION DETAILS

For the purpose of this PA, communications must be sent to the following addresses:

If to the Commission:
European Commission Directorate-General for Health and Food Safety
E-mail: SANTE-PROCUREMENT@ec.europa.eu

If to a Participating Member State – See details in Vaccine Order Form

19
By derogation from this Article I.9, different contact details for the Commission, the Participating Member States or the Contractor may be provided in Vaccine Order Form.

I.10 PROJECT MANAGEMENT

Pfizer, BioNTech and the Commission will each nominate a project manager that will be the sole contact point for and responsible for managing the overall relationship between the parties. Each Participating Member State shall in addition appoint an expert to work on PA implementation at Participating Member State level. Project meetings with the Commission and Participating Member State experts will be held regularly on a timeframe to be determined following execution of the PA to report, amongst other things, on progress of clinical studies, licensing activities, manufacturing status, forecast and deliveries. Details specific to each Participating Member State such as logistics and payments shall be handled directly by the respective Participating Member State experts.

I.11 EXPLOITATION OF THE RESULTS OF THE PA

The Commission acknowledges and agrees [***] (collectively, the “Vaccine IP Rights”). [***]. All rights not expressly granted by the Contractor hereunder are reserved by the Contractor.

I.12 INDEMNIFICATION

The Commission, on behalf of the Participating Member States, declares that the use of Vaccines produced under this PA will happen under epidemic conditions requiring such use, and that the administration of Vaccines will therefore be conducted under the sole responsibility of the Participating Member States. [***].

I.13 APPLICABLE LAW AND SETTLEMENT OF DISPUTES

1.13.1 This PA shall be governed by the laws of Belgium. [***]

I.14 OTHER SPECIAL CONDITIONS

The Contractor shall keep the Commission and the Participating Member States informed about [***] during the pharmacovigilance or vaccine monitoring programmes in relation to the Vaccines which are the object of this PA [***].

SIGNATURES

For the Contractor, [***][***][***].

For the Commission, on behalf and in the name of the Participating Member States, [forename/surname/position].

20
Signature:  
Done at [place], [date]

In duplicate in English.
II. GENERAL CONDITIONS FOR THE FRAMEWORK CONTRACT

II.1 DEFINITIONS

All definitions are contained in Article I.2 or in the relevant provisions of this PA.

II.2 ROLES AND RESPONSIBILITIES IN THE EVENT OF A JOINT TENDER

In the event of a joint tender submitted by a group of economic operators and where the group does not have legal personality or legal capacity, one member of the group is appointed as leader of the group.

II.3 SEVERABILITY

Each provision of this PA is severable and distinct from the others. If a provision is or becomes illegal, invalid or unenforceable to any extent, it must be severed from the remainder of the PA. This does not affect the legality, validity or enforceability of any other provisions of the PA, which continue in full force and effect. The illegal, invalid or unenforceable provision must be replaced by a legal, valid and enforceable substitute provision which corresponds as closely as possible with the actual intent of the parties under the illegal, invalid or unenforceable provision. The replacement of such a provision must be made in good faith between the parties. The PA must be interpreted as if it had contained the substitute provision as from its entry into force.

II.4 PROVISION OF SERVICES AND SUPPLIES

II.4.1 All periods specified in the PA are calculated in calendar days, unless otherwise specified.

II.4.2 The Contractor must immediately inform the Commission of any changes in the exclusion situations as declared, according to Article 137 (1) of Regulation (EU) 2018/1046.

II.5 COMMUNICATION BETWEEN THE PARTIES

II.5.1 Form and means of communication

Any formal notification under the PA must:

(a) be made in writing in paper or electronic format in the language of the contract;

(b) bear the PA number and, if applicable, the Vaccine Order Form number;

(c) be made using the relevant communication details set out in Article I.9; and

(d) be sent by mail or email.

If a party requests written confirmation of an e-mail within a reasonable time, the other party must provide an original signed paper version of the communication as soon as possible.

The parties agree that any communication made by email has full legal effect and is admissible as evidence in judicial proceedings.
II.5.2 Date of communications by mail and email

Any communication is deemed to have been made when the receiving party receives it, unless this PA refers to the date when the communication was sent.

E-mail is deemed to have been received by the receiving party on the day of dispatch of that e-mail, provided that it is sent to the e-mail address indicated in Article I.9. The sending party must be able to prove the date of dispatch. In the event that the sending party receives a non-delivery report, it must make every effort to ensure that the other party actually receives the communication by email or mail. In such a case, the sending party is not held in breach of its obligation to send such communication within a specified deadline.

Mail sent to the Commission or the Participating Member State is deemed to have been received on the date on which the department responsible referred to in Article I.9 registers it.

Formal notifications are considered to have been received by the receiving party on the date of receipt indicated in the proof received by the sending party that the message was delivered to the specified recipient.

II.6 LIABILITY

II.6.1 During the term of this PA, [***].

II.6.2 [***].

II.6.3 The Commission and the Participating Member States shall [***] to mitigate both (1) the damages that would otherwise be recoverable from the other or the Contractor pursuant to this PA and the Vaccine Order Forms, and (2) any costs, fees, expenses or losses that may be incurred by the Commission or the Participating Member State, or for which the Contractor may be responsible, under this PA and/or any Vaccine Order Form, by taking appropriate and reasonable actions to reduce or limit the amount of such damages, costs, fees, expenses or losses.

II.6.4 Limits on liability

(i) Taking into account the unprecedented nature of the current COVID-19 situation and the exceptional circumstances under which the Vaccine shall be delivered, the parties explicitly agree that [***].

(ii) [***]

(iii) The Contractor shall not be liable for any breach or non-compliance of this PA solely and exclusively towards the Participating Member State or any third parties acting on its behalf, whenever that Participating Member State or third parties acting on its behalf acted in breach of the Participating Member State’s obligations under this PA or any Vaccine Order Form;

(iv) The aggregate liability of the Contractor and its Affiliates towards the Commission arising out of or relating to this PA and/or the Vaccine Order Forms (whether arising contractually or extra-contractually), shall not exceed [***].
The liability of the Contractor and its Affiliates towards the Participating Member States arising out of or relating to this PA and/or any Vaccine Order Form concluded with a Participating Member State (whether arising contractually or extra contractually), shall not exceed [***].

II.6.5 No limitation of liability
Nothing in this PA excludes or limits the liability of either party for:
[***]

II.6.6 Waiver of sovereign immunity
Each Participating Member State represents that it has adequate statutory or regulatory authority and adequate funding appropriation to undertake and completely fulfil the indemnification obligations pursuant to Article I.12 of this PA.

II.6.7 Recall
In the event of a recall of the Vaccine, [***].

II.7 CONFLICT OF INTEREST AND PROFESSIONAL CONFLICTING INTERESTS
II.7.1 The Contractor must take all the necessary measures to prevent any situation of conflict of interest or professional conflicting interest.

II.7.2 The Contractor must notify the Commission in writing as soon as possible of any situation that could constitute a conflict of interest or a professional conflicting interest during the Implementation of the PA. The Contractor must immediately take action to rectify the situation.

The Commission may do any of the following:
(a) verify that the Contractor’s action is appropriate;
(b) require the Contractor to take further action within a specified deadline;
(c) decide not to award a Vaccine Order Form to the Contractor.

II.7.3 The Contractor must pass on all the relevant obligations in writing to:
(a) its personnel which is directly involved in the performance of this PA;
(b) any natural person with the power to represent it or take decisions on its behalf;
(c) third parties involved in the Implementation of the PA, including subcontractors.

The Contractor must also ensure that the persons referred to above are not placed in a situation which could give rise to conflicts of interest.
II.8 Representations and warranties

II.8.1 Mutual representations and warranties

The parties each represent and warrant to each other the following:

(i) Organization and authority. They have full right, power and authority to enter into this PA and to perform their respective obligations under this PA;

(ii) No conflicts or violations. The execution and delivery of this PA by such party and the performance of such party’s obligations hereunder (i) do not conflict with or violate any laws existing as of the date of entry into force of the PA and applicable to such party and (ii) do not and will not conflict with, violate, breach or constitute a default under, and are not prohibited or materially restricted by, any contractual obligations of such party; [* * * ]; and

(iii) Valid execution. Such party is duly authorised to execute and deliver this PA, and the person executing this PA on behalf of such party is duly authorised to execute and bind such party to the terms set forth herein.

The above warranties shall also be given by the Participating Member States in respect of the Vaccine Orders Forms and their obligations contained therein.

II.8.2 Warranties of the other party

The Contractor warrants to the Commission and the Participating Member States that:

[***]

[***]

In the event of any breach of the Contractor’s warranties or undertakings relating to the Vaccine, the Commission’s and the Participating Member States’ [* * * ].

The Commission and the Participating Member State warrant that the PA is awarded and each Vaccine Order Form is concluded in accordance with applicable Laws.

[***]

II.8.3 Anti-bribery/anti-corruption

The parties represent and warrant that, beyond the mutual consideration set forth in this PA, neither they nor their agents have provided or requested, or will provide or request, any additional incentive or benefit to or from the other party or its agents to induce either party to enter into this PA or perform any part of this PA.

The Contractor has not made, and will not make, in the performance of this PA directly or indirectly any payment, offer, promise, or authorisation of payment of money or anything of value to a government official, political party, candidate for political office, or any other person, and has not sought and will not seek improperly or corruptly to influence any government official, political party, candidate for political office, or any other person, in order to gain an improper business advantage.

25
II.8.4 No other warranty

Except to the extent set out expressly in this PA, all conditions, warranties or other terms which might have effect between the parties or be implied or incorporated into this PA (whether by statute, common law or otherwise) are hereby excluded to the fullest extent permitted by applicable Law. [***].

II.9 CONFIDENTIALITY

II.9.1 Neither the Commission, a Participating Member State nor the Contractor shall, at any time, without the disclosing party’s prior written consent, disclose to any third party any of the other party’s Confidential Information.

II.9.2 The Commission, the Participating Member State and the Contractor shall:

(a) use such Confidential Information solely for the purposes for which it was provided;
(b) take all reasonable precautions to prevent any unauthorised use or disclosure;
(c) not disclose or distribute any Confidential Information to any third party except as and to the extent authorised in writing to do so by the disclosing party.

II.9.3 The receiving party shall be permitted to disclose Confidential Information that is required or requested to be disclosed by a governmental authority pursuant to applicable law in connection with any other legal or administrative proceeding, provided that it (i) notifies the disclosing party of any such disclosure requirement or request as soon as practicable and (ii) furnishes only that portion of the Confidential Information which, in the opinion of the receiving party or their legal counsel, is responsive to such requirement or request and (iii) asks the court or other public body, if applicable, to treat the Confidential Information as confidential.

II.9.4 The receiving party shall disclose Confidential Information only to such of its representatives who have a need to know such Confidential Information to fulfill its obligations under this PA; provided, however, before any disclosure of Confidential Information, the receiving party shall bind its representatives receiving such Confidential Information to a written agreement of confidentiality at least as restrictive as contained in this PA; and prior to any disclosure, the receiving party shall instruct its representatives of the confidential nature of, and to maintain the confidentiality of, the Confidential Information. The receiving party shall be responsible for all actions of its representatives, including any breach of the terms hereof, regardless of whether or not such representatives remain employed or in contractual privity with the receiving party.

II.9.5 Notwithstanding the foregoing, in all cases, [***] the Contractor may disclose Confidential Information to their Affiliates without prior written consent of the Participating Member States.

II.9.6 The confidentiality obligations set out in this Article II.9 are binding on the Commission, the Participating Member State and the Contractor during the Implementation of the PA and for as long as the information or documents remain confidential unless:
II.9.7 The Contractor must obtain from any natural person with the power to represent it or take decisions on its behalf, as well as from third parties involved in the Implementation of the PA a commitment that they will comply with this Article. At the request of the Commission, the Contractor must provide a document providing evidence of this commitment.

II.9.8 Neither this PA nor the performance by either party hereunder shall transfer to the receiving party any proprietary right, title, interest or claim in or to any of the disclosing party’s Confidential Information (including, but not limited to, any intellectual property rights subsisting therein) or be construed as granting a license in its Confidential Information.

II.9.9 The provisions of this Article II.9 shall survive the termination or expiration of this PA for [***], except with respect to any information that constitutes a trade secret (as defined by the applicable Law), in which case the recipient of such information will continue to be bound by its obligations under this Article II.9 for so long as such information continues to constitute a trade secret, but in no event for a period of less than [***] specified above.

II.9.10 The Contractor acknowledges that the Commission is subject to requirements laid down under Regulation (EC) 1049/2001. The Commission commits that it will consult with the Contractor on any disclosure request concerning documents containing Confidential Information as provided for in Article 4(4) of said Regulation.

II.10 ANNOUNCEMENTS AND PUBLICITY

The parties shall consult together on the timing, contents and manner of any press release relating to the execution of this PA. Other than the foregoing, no party shall make, or permit any person to make, any public announcement concerning the existence, subject matter or terms of this PA or a Vaccine Order Form, the wider transactions contemplated by them, or the relationship between the parties, without the prior written consent of the other party (such consent not to be unreasonably withheld or delayed), except (i) as required by law, any governmental or regulatory authority (including, without limitation, any relevant securities exchange), any court or other authority of competent jurisdiction; or (ii) on terms that are consistent and do not go further than the matters covered in any agreed press release. For clarity, unless consent is granted pursuant to this Article II.10, no announcement or disclosure will [***].

A party shall not use the name, trade name, service marks, trademarks, trade dress or logos of the other party in publicity releases, advertising or any other publication, without the other party’s prior written consent in each instance, provided, however, that consent is granted for public announcements pursuant to above sub-clause (ii) in this Article II.10.
II.11 Processing of personal data by the Commission

Any personal data included in or relating to the PA, including its implementation, shall be processed in accordance with Regulation (EU) 2018/1725. Such data shall be processed solely for the purposes of the implementation, management and monitoring of the PA by the data controller. For the purpose of this provision, the data controller for the Commission shall be the Director-General of the European Commission’s Directorate-General for Health and Food Safety. The data protection notice is available at https://ec.europa.eu/info/data-protection-public-procurement-procedures_en.

The Contractor or any other person whose personal data is processed by the data controller in relation to this PA has specific rights as a data subject under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access, rectify or erase their personal data and the right to restrict or, where applicable, the right to object to processing or the right to data portability.

Should the Contractor or any other person whose personal data is processed in relation to this PA have any queries concerning the processing of its personal data, it shall address itself to the data controller. They may also address themselves to the Data Protection Officer of the data controller. They have the right to lodge a complaint at any time to the European Data Protection Supervisor.

II.11.2 Processing of personal data by the Contractor

The processing of personal data by the Contractor shall meet the requirements of Regulation (EU) 2016/679 and be processed solely for the purposes set out by the controller.

II.12 SUBCONTRACTING

II.12.1 The Contractor may not subcontract and have the PA implemented by third parties beyond the third parties already mentioned in its tender [***].

II.12.2 In the case of subcontracting, the Contractor remains bound by its contractual obligations and is solely responsible for the Implementation of the PA.

II.12.3 The Contractor must ensure that the subcontract does not affect the rights of the Commission and the Participating Member States under this PA.

II.13 [***] AMENDMENTS

II.13.1 Any amendment to the PA or a Vaccine Order Form must be made in writing before all contractual obligations have been fulfilled. A Vaccine Order Form does not constitute an amendment to the PA.

II.13.2 No amendment can make changes to the PA or a Vaccine Order Form that might alter the initial conditions of the procurement procedure or result in unequal treatment of tenderers or contractors.
II.14 ASSIGNMENT

Neither this PA nor any interest hereunder will be assignable by a party without the prior written consent of the other party, except as follows: [***].

Neither this PA nor any interest hereunder will be assignable by a party without the prior written consent of the other party, except as follows: Force majeure.

II.14.1 If a party is affected by Force majeure, it must immediately notify the other party, stating the nature of the circumstances, their likely duration and foreseeable effects.

II.14.2 A party is not liable for any delay or failure to perform its obligations under the PA or Vaccine Order Form if that delay or failure is a result of Force majeure. [***].

II.14.3 The parties must take all necessary measures to limit any damage due to Force majeure and shall use commercially reasonable efforts to avoid or minimize the delay in performance of their respective obligations affected by Force majeure.

II.15 SUSPENSION OF THE IMPLEMENTATION OF THE PA

II.15.1 Suspension by the Contractor

If the Contractor or a Participating Contractor Affiliate is affected by Force majeure, it may suspend the provision of the services under a Vaccine Order Form.

The Contractor or the Participating Contractor Affiliate must immediately notify the Commission of the suspension. The notification must include a description of the Force majeure and state when the Contractor or the Participating Contractor Affiliate expects to resume the provision of services.

The Contractor or the Participating Contractor Affiliate must notify the Commission as soon as it is able to resume performance of the Vaccine Order Form, unless the Commission has already terminated the PA or the Vaccine Order Form.

II.15.2 Suspension by the Commission or the Participating Member State

Pursuant to the Financial Regulation, the Commission or the Participating Member State may suspend the implementation of the PA or performance of a Vaccine Order Form or any part of it:

(a) if the procedure for awarding the PA or a Vaccine Order Form or the implementation of the PA proves to have been subject to Irregularities, Fraud (in the sense of the Financial Regulation) or breach of obligations;

(b) in order to verify whether the presumed Irregularities, Fraud (in the sense of the Financial Regulation) or breach of obligations have actually occurred.

The Commission or the Participating Member State in question must formally notify the Contractor of the suspension and the reasons for it. Suspension takes effect on the date of formal notification, or at a later date if the formal notification so provides.

The Commission or the Participating Member State in question must notify the Contractor as soon as the verification is completed whether:
(a) it is lifting the suspension; or
(b) it intends to terminate the PA or a Vaccine Order Form under Article II.16.1, (f) or (i).

The Contractor is not entitled to compensation for suspension of any part of the PA or a Vaccine Order Form. For the avoidance of doubt, the Contractor shall not be under any obligation to deliver any Contracted Doses or the Additional Order during the suspension period, and the Delivery Schedule shall be adjusted to take into account the period of such suspension. Equally for the avoidance of doubt, the Contractor shall complete the delivery of any Contracted Doses or Additional Order that were already in transit on the date of the formal notification or at the later date indicated in the formal notification.

II.16 TERMINATION OF THE PA

II.16.1 Grounds for termination by the Commission

The Commission may terminate the PA or the Participating Member State may terminate any on-going Vaccine Order Form (depending on whether the event affects the PA or the Vaccine Order Form) solely in the following circumstances:

(a) [***].

(b) if the Contractor does not implement the PA or perform the Vaccine Order Form in accordance with material aspects of the PA or the Vaccine Order Form (as applicable) or is otherwise in material breach of another substantial contractual obligation;

(c) [***].

(d) if the Contractor or any person that assumes unlimited liability for the debts of the Contractor is in one of the situations provided for in points (a) and (b) of Article 136(1) of the Financial Regulation;

(e) if the Contractor or any Related person is in one of the situations provided for in points (c) to (h) of Article 136(1) or Article 136(2) of the Financial Regulation;

(f) if the procedure for awarding the PA or the Implementation of the PA proves to have been subject to Irregularities, Fraud (in the sense of the Financial Regulation) or breach of obligations;

(g) if the Contractor is in a situation that does constitute a Conflict of interest or a Professional conflicting interest which would have a material adverse impact on the performance of the PA;

(h) in case of a change regarding the exclusion situations listed in Article 136 of Regulation (EU) 2018/1046 that calls into question the decision to award the contract;

(i) [***].

II.16.2 Grounds for termination by the Contractor

The Contractor may terminate the PA or any on-going Vaccine Order Form solely in the following circumstances:

(a) if the Commission or the Participating Member State does not implement the PA or does not perform the Vaccine Order Form in accordance with material aspects of the

---

II.16.3 Procedure for termination

A party must formally notify the other party of its intention to terminate the PA or a Vaccine Order Form and the grounds for termination. The other party has [***] following the date of receipt to submit observations, including the measures it has taken or will take to continue fulfilling its contractual obligations. Failing that, the decision to terminate becomes enforceable the day after the time limit for submitting observations has elapsed in the event the grounds giving rise to termination have not been cured.

If the other party submits observations, the party intending to terminate must formally notify it.

II.16.4 Effects of termination

[***] of the date of termination, the Contractor must submit any invoice required for services that were provided before the date of termination.

The termination or expiration of this PA shall not affect the survival and continuing validity of Articles I.1, I.2, I.4, I.6.2 (so far as it concerns resale and donation), I.6.7, I.6.9, I.6.11, I.6.12, I.6.14, I.6.16, I.7 to I.9, I.11 to I.14, I.15, I.16, I.18 to I.20, Attachment 3 (Delivery Specification) and Attachment 5 (Return and Disposal of Product Materials) or of any other provision which is expressly or by implication intended to continue in force after such termination or expiration.

Expiry or termination of this PA for any reason shall be without prejudice to either party’s other rights and remedies or to any accrued rights and liabilities as the date of such expiry or termination; [***]

II.17 Invoices, Value Added Tax and e-invoicing

II.17.1 Invoices and value added tax

Invoices must contain the Contractor’s or the Participating Contractor Affiliate’s (or leader’s in the case of a joint tender) identification data, the amount, the currency and the date, as well as the PA reference and reference to the Vaccine Order Form.

Invoices must indicate the place of taxation of the Contractor or the Participating Contractor Affiliate (or leader in the case of a joint tender) for value added tax (VAT) purposes and must specify separately amounts not including VAT and amounts including VAT.

It is understood and agreed between the parties that any prices stated under this PA and Vaccine Order Form are exclusive of any VAT or similar tax and all other taxes which are incurred as a result of manufacturing and supplying the Product (including custom duties, levies and charges and all local taxes) (“Taxes”), which shall be added thereon as applicable. Where Taxes are properly chargeable on any amounts payable under this PA or Vaccine Order Form, the party making the payment will pay the amount of Taxes, as specified on the invoice, in accordance with the laws and regulations of the country in which the Taxes are chargeable.

31
II.18 PAYMENTS AND GUARANTEES

II.18.1 Date of payment
The date of payment is deemed to be the date on which [***]

II.18.2 Currency
Payments are made in euros or, for non-Eurozone countries, the local functional currency of the Participating Member State. For non-Eurozone countries, the Vaccine Order Form shall set forth the Delivery Price in the local functional currency converted from euro at the exchange rate existing one (1) day prior to the Effective Date of the PA as of 4:00pm London time published in Bloomberg FX Fixings (BFX), such rates being found via Bloomberg or the website www.bloomberg.com/markets/currencies/fx-fixings.

II.18.3 Costs of transfer
The costs of the transfer are borne as follows:
(a) the Commission or the Participating Member State in question bears the costs of dispatch charged by its bank;
(b) the Contractor or the Participating Contractor Affiliate bears the costs of receipt charged by its bank;
(c) the party causing repetition of the transfer bears the costs for repeated transfer.

II.18.4 Suspension of the time allowed for payment
The Commission or the Participating Member State in question may suspend the payment periods specified in Article I.8 at any time by notifying the Contractor or the Participating Contractor Affiliate (or leader in the case of a joint tender) that its invoice cannot be processed.

II.18.5 Interest on late payment
On expiry of the payment periods specified in Article I.8, the Contractor or the Participating Contractor Affiliate (or leader in the case of a joint tender) is entitled to interest on late payment at the higher of:
(a) the rate applied by the European Central Bank for its main refinancing operations in euros (the reference rate) [***] (or such centralized bank reference rate set forth...
in the Vaccine Order Form) and (b) [***] The reference rate is the rate in force, as published in the C series of the Official Journal of the European Union, on the first day of the month in which the payment period ends.

Suspension of the payment period as provided for in Article II.18.4 is not considered as giving rise to late payment.

Interest on late payment covers the period running from the day following the due date for payment up to and including the date of payment as defined in Article II.18.1.

II.19 RECOVERY

II.19.1 Recovery procedure

In all cases where the recovery procedure as described in the Financial Regulation applies, the parties shall follow the procedure set out in this Article.

Before recovery, the Commission or the Participating Member State in question must formally notify the Contractor of its intention to recover the amount it claims, specifying the amount due and the reasons for recovery and inviting the Contractor to make any observations [***].

If no observations have been submitted or if, despite the observations submitted, the Commission or the Participating Member State in question decides to pursue the recovery procedure, it must confirm recovery by formally notifying a debit note to the Contractor, specifying the date of payment. The Contractor must pay in accordance with the provisions specified in the debit note.

If the Contractor does not pay by the due date, the Commission or the Participating Member State in question may, after informing the Contractor in writing, recover the amounts due:

(a) by offsetting them against any amounts owed to the Contractor by the Commission or the Participating Member State in question;
(b) by taking legal action.

II.19.2 Interest on late payment

If the Contractor does not honour the obligation to pay the amount due by the date set by the Commission or the Participating Member State in question, the amount due bears interest at the rate indicated in Article II.18.5. Interest on late payments will cover the period starting on the day after the due date for payment and ending on the date when the Commission or the Participating Member State in question receives the full amount owed.

Any partial payment is first entered against charges and interest on late payment and then against the principal amount.

II.20 CHECKS AND AUDITS

II.20.1 The Commission and the European Anti-Fraud Office may check or require an audit on the implementation of the PA. This may be carried out either by OLAF’s own staff or by any outside body authorised to do so on its behalf, provided that the auditor may not be a competitor of the Contractor.
Such checks and audits may be initiated at any moment during business hours during the provision of the services and up to [***] starting from the payment of the balance of the last specific contract issued under this PA.

The audit procedure is initiated on the date of receipt of the relevant letter sent by the Commission. Audits are carried out on a confidential basis.

II.20.2 The Contractor must keep all original documents stored on any appropriate medium, including digitised originals if authorised under national law, for a period of [***] starting from the payment of the balance of the last specific contract issued under this PA.

II.20.3 The Contractor must grant the appropriate right of access to sites and premises where the PA is implemented, [***], needed to conduct such checks and audits. The Contractor must ensure that the information is readily available at the moment of the check or audit and, if so requested, that information is handed over in an appropriate format. The auditor must, insofar possible, comply with all applicable and reasonable security measures notified to Commission by the Contractor subject to this not creating any material obstacles for the performance of the auditor’s tasks.

II.20.4 On the basis of the findings made during the audit, a provisional report is drawn up. The Commission or its authorised representative must send it to the Contractor, who has [***] following the date of receipt to submit observations. The Contractor must receive the final report within [***] following the expiry of the deadline to submit observations.

On the basis of the final audit findings, the Participating Member State in question may recover all or part of the payments made in accordance with Article II.19 and may take any other measures which it considers necessary.

II.20.5 In accordance with Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspection carried out by the Commission in order to protect the European Communities’ financial interests against fraud and other irregularities and Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office, the European Anti-Fraud Office may carry out investigations, including on the spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity under the contract affecting the financial interests of the Union. Findings arising from an investigation may lead to criminal prosecution under national law.

The investigations may be carried out at any moment during the provision of the services and up to [***] starting from the payment of the balance of the last specific contract issued under this PA.

II.20.6 The Court of Auditors and the European Public Prosecutor’s Office established by Council Regulation (EU) 2017/1939 (“the EPPO”) have the same rights as the Commission, particularly right of access, for the purpose of checks, audits and investigations.
II.21 RELATIONSHIP OF THE PARTIES

The relationship hereby established between the Contractor and the Commission is solely that of independent contractors. Neither party has authority to act or make any agreements or representations on behalf of the other party. This PA is not intended to create, and shall not be construed as creating, between the parties, the relationship of principal and agent, employer and employee, joint venturers, co-partners, or any other such relationship, the existence of which is expressly denied.

II.22 WAIVER

A waiver by any party of any term or condition of this PA in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach thereof. All remedies specified in this PA shall be cumulative and in addition to any other remedies provided at Law or in equity, except where expressly otherwise agreed.

II.23 FURTHER DOCUMENTS

Each party hereto agrees to execute such further documents and take such further steps as may be reasonably necessary or desirable to effectuate the purposes of this PA.

II.24 HEADINGS

Headings of Articles or other parts of this PA are included herein for convenience of reference only and shall not constitute a part of this PA or change the meaning of this PA.

II.25 ELECTRONIC DELIVERY AND STORAGE

Delivery of a signed PA by reliable electronic means, including facsimile or email (with receipt electronically confirmed), shall be an effective method of delivery of the executed PA. This PA may be stored by electronic means and either an original or an electronically stored copy of this PA can be used for all purposes, including in any proceeding to enforce the rights or obligations of the parties to this PA.

II.26 ENTIRE AGREEMENT

This PA, together with any Annexes and Attachments, which are hereby incorporated by reference, constitute the entire agreement of the parties with respect to its subject matter and merges and supersedes all prior discussions and writings with respect to thereto.

II.27 COSTS

Each party will bear its own legal costs in preparing and concluding this PA.
This Vaccine Order Form is submitted by:

[The Government of [•]] (the “Participating Member State”), represented for the purposes of signing this Vaccine Order Form by [forename, surname, function, department of authorising officer],

to:

Pfizer Inc, incorporated in Delaware (Registration Number 0383418) with its registered address at 235 East 42nd Street, 10017 New York City, NY (UNITED STATES) (“Pfizer”),

and

BioNTech Manufacturing GmbH, registered with the commercial register of the lower court (Amtsgericht) of Mainz, Germany under HRB 47548, with its registered address at An ger Goldgrube 12, 55131 Mainz, Germany (“BioNTech”), (Pfizer and BioNTech together the “Contractor”), represented for the purposes of signing this Vaccine Order Form by [***]

The Participating Member State and Contractor are together referred to as the “Parties” and each individually as a “Party”.

WHEREAS

- Contractor and the European Commission, acting on behalf of and in the name of the Participating Member States, entered into a Purchase Agreement for the purchase and supply of Contractor’s Vaccine for EU Member States dated [•] 2021 (the “PA”), the terms of which are binding on the Participating Member States and must be read in conjunction with this Vaccine Order Form.

- In accordance with Article I.5.2 and I.6.2 of the PA, the Participating Member State hereby places its order for its full allocated portion of the Contracted Doses or Additional Order (as applicable).
1. This Vaccine Order Form is submitted by the Participating Member State to Contractor in accordance with the terms of the PA, and forms an integral part of the PA. The terms and conditions of the PA are incorporated into this Vaccine Order Form by reference. In the event of contradiction between this Vaccine Order Form and the PA, the terms of the PA prevail regardless of any provision to the contrary. Any capitalised terms in this Vaccine Order Form will have the meaning attributed to them in the definitions list included in Article I.2 of the PA.

2. This Vaccine Order Form relates to the order for the Participating Member State’s full allocated portion of the Contracted Doses or the relevant Additional Order (as applicable) as set out in the allocation provided by the Commission to Contractor pursuant to Article I.6.2 of the PA. The submission of this signed Vaccine Order Form by the Participating Member State to Contractor constitutes a binding order by the Participating Member State for the purchase of its full allocated portion of the Contracted Doses or the relevant Additional Order (as applicable) in accordance with the details set out in the Appendix to this Vaccine Order Form.

3. By signature of this Vaccine Order Form, the undersigned Participating Member State warrants to Contractor that:
   a. it is irrevocably and unconditionally bound by the terms of the PA (as concluded by the Commission on behalf and in the name of the Participating Member States), including the indemnification obligations and the liability, limitation of liability and exclusions terms set out therein;
   b. the provisions of the PA are enforceable against it in accordance with its terms;
   c. it shall indemnify the Indemnified Persons in accordance with Article I.12 (Indemnification) of the PA;
   d. it has full right, power and authority to enter into this Vaccine Order Form and to perform its respective obligations under it;
   e. the person executing this Vaccine Order Form is duly authorized to execute and bind the undersigned Participating Member State to the terms set forth herein and incorporated by reference.

4. [***]
5. The Participating Member State represents and warrants that all necessary permissions and approvals have been or will be obtained prior to the time for performance by the Participating Member State, to authorise performance of all of the obligations contained herein.

6. Any change to the Appendix to this Vaccine Order Form requires to be agreed by the parties in writing or by email.

Article II
Delivery, Supply

1. **Delivery Address**: The Delivery Address(es) for the Participating Member State is as set out in the Appendix to this Vaccine Order Form.

2. **Supply of the Products**

   The Contractor shall supply the Products as further described in the PA. [Note: Include any additional details concerning the supply here.]

Article III
Invoices; Notices

1. **Invoice and Payments**: Contractor shall invoice the Participating Member State in accordance with the terms of the PA. All payments to Contractor or its designated Affiliate shall be made in accordance with the terms of the PA.

   Payment shall be made in the currency set out in the Appendix to this Vaccine Order Form.

2. **Notice**: Any notice given under this Vaccine Order Form must a) be made in writing in English in paper or electronic format; b) bear the PA number and the number of this Vaccine Order Form; c) be made using the relevant communication details set out in the Appendix to this Vaccine Order Form with respect to the Participating Member State and Contractor (as applicable); d) be sent by mail and email.

Article IV
Entry into Force and Duration

1. This Vaccine Order Form shall enter into force on the date of signature by the Parties and will remain into force until termination of the PA, or if the PA expires, until the last delivery of Product [***].
1. For the avoidance of doubt, Article I.13 (Applicable Law and Settlement of Disputes) of the PA shall apply to any dispute arising out of the implementation of or in connection with this Vaccine Order Form and the Participating Member State irrevocably agrees to be bound by the provisions set out therein.
a. Participating Member State will purchase [insert amount] number of doses of [Contracted Doses] [Additional Order] of the Vaccine, on the basis of the following delivery schedule: [***].

b. The price of [Contracted Doses] [Additional Order] is [***]. The total amount payable by the Participating Member State for the [Contracted Doses] [Additional Order] is [insert amount], [***].

c. The Delivery Address(es) are as follows:
[insert]

d. Payment shall be made in the following currency pursuant to the provisions of Article II.19.2 of the PA: [to be completed].

e. Details for notices
  Participating Member State:
  [Name of Participating Member State]
  [Full official address of Participating Member State]
  [Full name of addressee physical person (contact person)]
  [Function of addressee physical person (contact person)]
  E-mail: [complete email of addressee physical person (contact person)]

  Contractor:
  [Add details]

(Signature page follows)
SIGNATURES

For the Participating Member State,

[forename/surname/position]

Signature:_____________________

Done at [place], [date]

For acceptance of the Vaccine Order Form,

Contractor,

[***] Signature:_____________________

Done at [place], [date]

The invoice will be paid only once the Contractor has returned the signed Vaccine Order Form.
ANNEX II: AGREEMENT BETWEEN THE COMMISSION AND MEMBER STATES ON PROCUING COVID-19 VACCINES ON BEHALF OF THE MEMBER STATES AND RELATED PROCEDURES, ANNEXED TO THE COMMISSION DECISION C(2020) 4192 FINAL OF 18 JUNE 2020

Agreement

Preamble

Having regard to Article 4(5)(b) of Council regulation (EU) 2016/369 on the provision of emergency support within the Union as amended by Council regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak (hereinafter “ESI” or “ESI regulation

***

The European Commission (“the Commission”)

and

The following Member States: (XXX), hereinafter referred to as “the Participating Member States”

Together referred to as “the Parties”

Agree on the Following:

Article 1: Objective and mandate of the Commission

On the basis of the present agreement, the Commission is mandated to conclude, on behalf of the Participating Member States, Advance Purchase Agreements (“APA”) with vaccine manufacturers with the objective to procure vaccines for the purposes of combating the COVID-19 pandemic at Union level.

The Annex to this agreement sets out the negotiating directives for this purpose.

Article 2: Acquisition of vaccine doses

It is the Participating Member States, and not the Commission, that shall acquire vaccine doses from the manufacturers on the basis of the APAs unless otherwise agreed. All relevant vaccination policies shall therefore remain matters for the Participating Member States.

Article 3: APAs containing a right to acquire vaccine doses

Where the Commission concludes an APA in conformity with the present agreement that provides the right for the Participating Member States to acquire vaccine doses, the use of such a right shall take place by means of the conclusion of contracts between the Participating Member States and the vaccine manufacturers. There shall be no obligation for any Participating Member State to conclude such a contract on the basis of the APA. The APA shall contain a clause to this end.

Article 4: APAs containing an obligation to acquire vaccine doses

Where the Commission intends to conclude, in conformity with the present agreement, an APA containing an obligation to acquire vaccine doses, it shall inform the Participating Member States of such intention and the detailed terms. In case a Participating Member State does

42
not agree with the conclusion of an APA containing an obligation to acquire vaccine doses or its terms, it has the right to opt out by explicit notification to the Commission within 5 working days after the Commission has communicated its intention to conclude the APA. All Participating Member States not having opted out within the period of 5 working days are deemed to have authorised the Commission to negotiate and conclude the APA with the vaccine manufacturer in their name and on their behalf.

Article 5: The legally binding nature of APAs

Once concluded, the terms of the APA shall be legally binding on the Participating Member States, except for those who have exercised their right to opt out.

Article 6: Responsibility and liability

The present Agreement regulates only the division of potential liability and indemnification between the Commission and the Participating Member States. It does not regulate the extent to or the conditions under which potential liability of the vaccine manufacturer may be taken over or indemnified under the APAs.

The Commission shall be exclusively responsible for the procurement process and the conclusion of APAs including any liability arising out of the conduct of the negotiations.

Participating Member States acquiring a vaccine shall be responsible for the deployment and use of the vaccines under their national vaccination strategies, and shall bear any liability associated with such use and deployment. This shall extend to and include any indemnification of vaccine manufacturers under the terms and conditions of the relevant APA for liability related to the use and deployment of vaccines normally borne by such manufacturer.

Article 7: Obligation not to negotiate separately

By signing the present Agreement, the Participating Member States confirm their participation in the procedure and agree not to launch their own procedures for advance purchase of that vaccine with the same manufacturers.

In case an APA containing an obligation to acquire vaccine doses has been concluded with a specific manufacturer, the Member States having made use of the opt-out provided under the present Agreement can enter into separate negotiations with the same manufacturer after the APA under the present Agreement has been signed.

Annex

Initial considerations

A permanent solution to the COVID-19 crisis is most likely to be brought about by the development and deployment of a safe and effective vaccine against the virus. Every month gained in the deployment of a vaccine will save many lives, many jobs and billions of euros.

Therefore, it is the objective of the present Agreement that the EU takes steps to secure sufficient supplies of a safe and effective vaccine for Member States.

Structure and purpose of the procurement

Work on a COVID-19 vaccine is challenging for many reasons: the shortened development timeframe, the large upfront costs for manufacturers, the high failure rate during clinical trials. If vaccine producers follow their usual practice of making investments in production capacity only when they are sure of a viable product, this will result in considerably longer waiting times for a vaccine. Investments need to be made now in order to ensure that vaccines are being produced at the scale required as early as possible.
Under the present agreement, this challenge will be addressed through concluding EU-level Advance Purchase Agreements ("APA") with vaccine manufacturers when necessary, to secure access to vaccine candidates where they are successful, including up-front EU financing to de-risk essential investments to increase the speed and scale of manufacturing successful vaccines. Funding for the up-front payments will come from the Emergency Support Instrument (ESI).

The Parties understand that developing a safe and effective vaccine is a highly complex process and the risk of failure in any such venture is very high. Therefore, the aim is to put in place APAs with a number of manufacturers of leading vaccine candidates, to maximise the chances of having access to at least one successful vaccine.

The Commission will invite all vaccine manufacturers to manifest interest. In general, the Commission will give priority to negotiating specific APAs with those manufacturers that (a) have entered or have firm plans to enter clinical trials still in 2020, (b) have the capacity to develop a successful vaccine and (c) have a proven capacity to produce at scale already in 2021.

Process and governance

In order to run the procurement centrally and efficiently, the European Commission will set up a steering board for the process subject to Article 6 of the present Agreement. It will be co-chaired by the European Commission and a Participating Member State with experience in the negotiations and production capacities for vaccines. The steering board will include senior officials from all Participating Member States to assist and provide guidance throughout the evaluation process.

The co-chairs of the steering board will propose a team of a limited number of experts with relevant experience for the ongoing negotiations from six Participating Member States with production capacities for vaccines. These experts will join with the European Commission in a negotiation team ("joint negotiation team"), which will work on a continuous basis as one unit.

The joint negotiation team will start work immediately building on previous contacts with individual companies by the European Commission and Participating Member States. In order to launch negotiations with a specific manufacturer, there needs to be support from at least four Participating Member States. The joint negotiation team will make its best effort to take the advice of the steering board into account in the negotiations and will report back to the steering board on a regular basis on the progress made in negotiating with individual companies.

For compliance with the applicable rules, all members of the steering board and the joint negotiation team will obtain the status of experts associated to the procurement process as provided in the Financial Regulation. Given their access to highly sensitive business information, all those members will be required to sign strict confidentiality and no-conflict-of-interest agreements.

Assisted by the steering board, the European Commission will then decide which of the resulting APAs should be concluded, in particular if financing under ESI is insufficient to finance all relevant packages. The Commission will only consider those APAs for financing where at least four Participation Member States have expressed agreement. Before making any final decisions, the Commission will seek independent scientific advice on the state of progress and the available data on quality, safety and efficacy for the vaccine candidate in question.

Should financing under ESI be insufficient, Participating Member States can decide to top up ESI funding to make up the gap to finance all packages. In such a case where there are opportunities to conclude further APAs but money from ESI is no longer sufficient, Participating Member States will

44
have the opportunity to express their interest in such opportunities. If at least four Participating Member States express interest, those Participating Member States will make use of the possibility of a voluntary contribution to ESI to the required amount allowing the Commission to proceed with signing the APA only on behalf of those Member States that have expressed interest and contributed the funds to ESI.

For full transparency, the European Commission will report to the IPCR at least once every two weeks on overall progress more generally.

Advanced Purchase Agreements and conditions

To conclude APAs, the joint negotiating team will negotiate funding packages with individual vaccine producers in return for the right to buy a specific number of vaccine doses in a given timeframe and at a certain price.

As outlined in the present Agreement, the European Commission also has the possibility to conclude APAs including an obligation to procure the vaccine if it becomes available, where the conditions (notably the pricing) of those APAs make this worthwhile and in line with the conditions in the present Agreement. If in such a case the distinction between upfront payments and purchase price is difficult to draw, the Commission will share the total cost related to the vaccine purchase but will in any case contribute no more than 50% of the total cost.

Funding provided up front will be considered as an advance payment for any eventual purchase by Member States, thus reducing the amount that Member States will have to pay when eventually purchasing that vaccine.

The up-front payments under the APAs shall be used by manufacturers to de-risk the necessary investments related to both vaccine development and clinical trials, and the preparation of the at-scale production capacity along the entire vaccine production value chain in the EU required for a rapid deployment of millions of doses of an eventual vaccine. The relevant payments should be structured according to the need of the manufacturer, but subject to the state of the vaccine development, in particular relying on transparency of the associated clinical data and its assessment, at the time of payment. This is in order to avoid obligations to pay in situations where the development work has shown a vaccine candidate likely to be unsuccessful.

The purchase price of the vaccine, as well as the amount of funding provided up front will take into account a transparent estimation of production costs (supported by independent audits where available), as well as the resources already granted from other public sources. Under the APA, the manufacturer can be asked to provide ex post proof supported by independent audits concerning the activities financed by these payments.

The aim of the negotiation is to conclude APAs with individual companies under the best possible conditions. These APAs should specify details with respect to:

a) Payments to be made, such as payment amounts, payment schedules, type of payments requested and the use of those payments related to de-risk investment, financing clinical trials, providing working capital and scaling-up production capacity;

b) Delivery details of the vaccine if successful, such as price per person immunised (or alternatively, number of doses required per person immunised and price per dose), quantity of doses to be delivered and delivery timeline following approval, and

c) Any other relevant conditions, such as production capacity built or used in the EU or liability arrangements.
For liability arrangements, the joint negotiation team will make its best effort to limit what is required by individual companies for the purpose of indemnification to be included in the terms and conditions of the APA.

The APAs will contain provisions to clarify the law applicable to both the APA and resulting purchase orders as well as the competent courts. The Participating Member States agree that each APA negotiated by the Commission on their behalf with a vaccine manufacturer will have the same applicable law for all Participating Member States, and that the courts corresponding to that applicable law will be competent to hear disputes arising from that APA.

When taking a decision to finance individual APAs, the European Commission, in consultation with the steering board, will take into account the following elements: any available data on quality, safety and efficacy of the vaccine at time of negotiation of the contract, speed of delivery at scale, cost, risk-sharing, diversification of technologies, capacity to supply through development of production capacity within the EU, possible flexible future use of any capacity funded, engagement at an early stage with EU regulators with the intention to apply for an EU marketing authorisation for the candidate vaccine(s), commitment to supply vulnerable countries.

The procedure outlined above complies with the ESI Regulation and the Financial Regulation. The latter is aligned to the European procurement Directives, which also provide the basis for national procurement rules. Participating Member States may rely on the procedure run by the European Commission to directly purchase vaccines from the manufacturers as and when any of the vaccines becomes available based on the conditions laid down in the APA. Access to vaccine doses will be allocated to Participating Member States according to the population distribution key.

In the negotiations with the pharmaceutical industry under the present Agreement, the Commission will promote a Covid-19 vaccine as a global public good. This promotion will include access for low and middle income countries to these vaccines in sufficient quantity and at low prices. The Commission will seek to promote related questions with the pharmaceutical industry regarding intellectual property sharing, especially when such IP has been developed with public support, in order to these objectives. Any vaccines available for purchase under the APAs concluded but not needed and purchased by Participating Member States can be made available to the global solidarity effort.
<table>
<thead>
<tr>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal Republic of Germany</td>
</tr>
<tr>
<td>French Republic</td>
</tr>
<tr>
<td>Italian Republic</td>
</tr>
<tr>
<td>Kingdom of Spain</td>
</tr>
<tr>
<td>Republic of Austria</td>
</tr>
<tr>
<td>Hellenic Republic</td>
</tr>
<tr>
<td>Republic of Cyprus</td>
</tr>
<tr>
<td>Republic of Malta</td>
</tr>
<tr>
<td>Kingdom of Denmark</td>
</tr>
<tr>
<td>Kingdom of Sweden</td>
</tr>
<tr>
<td>Republic of Finland</td>
</tr>
<tr>
<td>Ireland</td>
</tr>
<tr>
<td>Portuguese Republic</td>
</tr>
<tr>
<td>Kingdom of Belgium</td>
</tr>
<tr>
<td>Grand Duchy of Luxembourg</td>
</tr>
<tr>
<td>Kingdom of the Netherlands</td>
</tr>
<tr>
<td>Republic of Poland</td>
</tr>
<tr>
<td>Romania</td>
</tr>
<tr>
<td>Republic of Bulgaria</td>
</tr>
<tr>
<td>Republic of Slovenia</td>
</tr>
<tr>
<td>Republic of Croatia</td>
</tr>
<tr>
<td>Czech Republic</td>
</tr>
<tr>
<td>Hungary</td>
</tr>
<tr>
<td>Slovak Republic</td>
</tr>
<tr>
<td>Republic of Lithuania</td>
</tr>
<tr>
<td>Republic of Latvia</td>
</tr>
<tr>
<td>Republic of Estonia</td>
</tr>
</tbody>
</table>
ANNEX IV: SUBCONTRACTORS

[***]
[***]
[***]

48
<table>
<thead>
<tr>
<th>Country</th>
<th>Participating Contractor Affiliate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>BioNTech Europe GmbH</td>
</tr>
<tr>
<td>France</td>
<td>Pfizer SAS</td>
</tr>
<tr>
<td>Italy</td>
<td>Pfizer S.r.l.</td>
</tr>
<tr>
<td>Spain</td>
<td>Pfizer S.L.U.</td>
</tr>
<tr>
<td>Austria</td>
<td>Pfizer Corporation Austria GmbH</td>
</tr>
<tr>
<td>Greece</td>
<td>Pfizer Hellas SA</td>
</tr>
<tr>
<td>Cyprus</td>
<td>Pfizer Export B.V.</td>
</tr>
<tr>
<td>Malta</td>
<td>Pfizer Export B.V.</td>
</tr>
<tr>
<td>Denmark</td>
<td>Pfizer ApS</td>
</tr>
<tr>
<td>Sweden</td>
<td>Pfizer Innovations AB</td>
</tr>
<tr>
<td>Finland</td>
<td>Pfizer Finland Oy</td>
</tr>
<tr>
<td>Ireland</td>
<td>Pfizer Healthcare Ireland</td>
</tr>
<tr>
<td>Portugal</td>
<td>Pfizer Biofarmaceutica Societate Unipessoal, Lda</td>
</tr>
<tr>
<td>Belgium</td>
<td>Pfizer SA</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>Pfizer Luxembourg S.A.R.L.</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Pfizer B.V.</td>
</tr>
<tr>
<td>Poland</td>
<td>Pfizer Export B.V. and Trading Polska sp. z o.o.</td>
</tr>
<tr>
<td>Romania</td>
<td>Pfizer Romania SRL</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>Pfizer Export B.V.</td>
</tr>
<tr>
<td>Slovenia</td>
<td>Pfizer Export B.V.</td>
</tr>
<tr>
<td>Croatia</td>
<td>Pfizer Export B.V.</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>Pfizer, spol. s r.o.</td>
</tr>
<tr>
<td>Hungary</td>
<td>Pfizer Gyógyszerkezelési Kft.</td>
</tr>
<tr>
<td>Lithuania</td>
<td>Pfizer Export B.V.</td>
</tr>
<tr>
<td>Latvia</td>
<td>Pfizer Export B.V.</td>
</tr>
<tr>
<td>Estonia</td>
<td>Pfizer Export B.V.</td>
</tr>
</tbody>
</table>

In addition, any Contractor Affiliate which is involved in the sale or distribution of Product which is resold or donated by a Participating Member State shall be deemed to be a Participating Contractor Affiliate.
Transfer of Source Code for MyMUT® Software Versions [***] on May 5th 2021

TRON gGmbH hereby transfers the full source code of the MyMUT® software versions [***] under the URL [***], encrypted zip archive (the “SOURCE CODE”); the key will be sent separately as a printout). With regard to the use of the data and the software by BioNTech SE, TRON recognizes that the software will be used for the so-called IVAC project.

Since the IVAC Supplementary Agreement dated January 1st 2015 between TRON and BioNTech expired on December 31st 2019 and no other related agreement between BioNTech SE and TRON gGmbH has been concluded so far, TRON hereby transfers these data (including inventions, rights to patent applications, patents and so-called trade secrets) subject to the rights of use to which TRON, TRON AFFILIATED COMPANIES and the respective cooperation partners are entitled in the IVAC Supplementary Agreement with the proviso that Sec. 6.4.1. of the Framework Collaboration Agreement ("WP5") between BioNTech SE and TRON gGmbH is applied as amended in Schedule 1, which amendment shall be effective solely for the purpose of this letter and the exploitation of the SOURCE CODE including any so called trade secret inventions contained in the SOURCE CODE. All other terms of the IVAC Supplementary Agreement shall remain unaffected. The parties further agree, via separate amendment, to extend the term of the IVAC Supplementary Agreement to Dec. 31st 2023.

BioNTech SE accepts this transfer under this letter agreement and recognizes the fulfillment of the obligations by TRON according to the IVAC Supplementary Agreement with regard to the above data.

06.05.2021
Mainz,

/s/ Michael Föhlings

/s/ Michael Föhlings

05.05.2021
Mainz,

/s/ Dr. Andrée Rothermel

/s/ Dr. Andrée Rothermel

/s/ Sierk Poetting

/s/ Sierk Poetting

Seite 1/3

/ TRON – Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH

Bankverbindung: Mainzer Volksbank eG, IBAN: [***], BIC: [***]

Amtsgericht Mainz: HRB 43191 - USt.-Id.Nr.: DE 269156552

[***]
This Amendment is agreed by the PARTIES for the sole purpose of regulating the remuneration payable by the relevant BIONTECH PARTY to TRON for the exploitation of a TRADE SECRET INVENTION to the extent any such TRADE SECRET INVENTION is part of the source code of the MyMUT® software versions L and M under the URL [***] encrypted zip archive (the “SOURCE CODE”). For this purpose only, Sec. 6.4.1 of the Framework Collaboration Agreement (“WP5”) will read as follows:

“For the WP5 CONTRACTUAL PRODUCTS sold by it or its licensees (or sublicensees) to THIRD PARTIES which fall within the scope of protection of a VALID CLAIM of a WP5 PROJECT PATENT or a TRADE SECRET INVENTION, the BIONTECH PARTY shall pay TRON remuneration to the amount of:

(i) [***] percent ([***]) of the WP5 CONTRACTUAL PRODUCT’s NET SELLING PRICE up to an annual aggregate worldwide NET SELLING PRICE per WP5 CONTRACTUAL PRODUCT of [***]) euro (€[***]); and
(ii) [***] percent ([***]) of the WP5 CONTRACTUAL PRODUCT’s NET SELLING PRICE if the annual aggregate worldwide NET SELLING PRICE per WP5 CONTRACTUAL PRODUCT exceeds [***]) euro (€[***]).

The aforementioned remuneration under this clause 6.4.1 shall be paid on a country-by-country basis for so long as the relevant WP5 CONTRACTUAL PRODUCT is covered by a VALID CLAIM of a WP5 PROJECT PATENT in the country of sale.

If a WP5 CONTRACTUAL PRODUCT falls within the scope of a TRADE SECRET INVENTION, it is the mutual expectation of the PARTIES that the exploitation of such TRADE SECRET INVENTION will be coherent and jointly together with the exploitation of one or more WP5 PROJECT PATENTS. Based on that understanding, the royalty pursuant to this clause 6.4.1 for the use of a TRADE SECRET INVENTION shall only be payable (x) if the relevant WP5 CONTRACTUAL PRODUCT also falls within the scope of protection of a VALID CLAIM of a WP5 PROJECT PATENT or, (y) in the event that the BIONTECH PARTY should exploit a TRADE SECRET INVENTION by entering into an agreement with a THIRD PARTY, if the relevant WP5 CONTRACTUAL PRODUCT also falls within the scope of protection of a VALID CLAIM of a patent (co)owned by such THIRD PARTY (“THIRD PARTY PATENT”).

The royalty is payable, on a WP5 CONTRACTUAL PRODUCT-by-WP5 CONTRACTUAL PRODUCT basis, only once per WP5 CONTRACTUAL PRODUCT, even if a WP5 CONTRACTUAL PRODUCT falls within the scope of protection of several WP5 PROJECT PATENTS and/or TRADE SECRET INVENTIONS.
For the avoidance of doubt, the sentence in Sec. 6.4.1. of the Framework Collaboration Agreement “WP5”) starting “If such exploitation is undertaken…..” shall be deleted in its entirety.

For all other purposes the original version of Sec. 6.4.1 shall remain unchanged, in full effect and shall not be affected by the aforementioned amendment.
THE SYMBOL “[***]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.

SIXTH AMENDMENT TO LEASE AGREEMENT

THIS SIXTH AMENDMENT TO LEASE AGREEMENT (this “Sixth Amendment”) is dated August 2, 2021 and hereby effective as of August 4, 2021 (“Effective Date”), between TECH PARK 270 III, LLC, a Maryland limited liability company, having an address at 26 North Euclid Avenue, Pasadena, California 91101 (“Landlord”), and BIONTECH US INC., a Delaware corporation, having an address at Suite 110, 40 Erie Street, Cambridge, Massachusetts 02139 (“Tenant”).

RECEITALS

A. Landlord and Kite Pharma, Inc., a Delaware corporation (“Kite”), have entered into that certain Lease Agreement (“Original Lease”) dated as of December 1, 2017, as amended and/or affected by that certain First Amendment to Lease Agreement dated January 29, 2018 (“First Amendment”), that certain Second Amendment to Lease Agreement dated February 26, 2018 (“Second Amendment”), that certain Third Amendment to Lease Agreement dated September 24, 2018 (“Third Amendment”) that certain Fourth Amendment to Lease Agreement dated May 23, 2019 (“Fourth Amendment”), that certain Fifth Amendment to Lease Agreement dated July 7, 2020 (“Fifth Amendment”), that certain Expansion Premises Work Letter dated July 7, 2020 (“Work Letter”), that certain letter agreement dated June 23, 2020 (the “June Letter Agreement”), that certain letter agreement dated July 23, 2020 (“July Letter Agreement”), and that certain that certain Acknowledgement of Commencement Date dated December 7, 2020 (“Acknowledgment of Commencement Date” and, together with the Original Lease, the First Amendment, the Second Amendment, the Third Amendment, the Fourth Amendment, the Fifth Amendment, the Work Letter, the June Letter Agreement and the July Letter Agreement, the “Lease”), wherein Landlord leased to Tenant approximately [***] rentable square feet (“Premises”) located at Suite 200, 930 Clopper Road, Gaithersburg, Maryland 20878-1301, as more particularly described in the Lease.

B. Landlord, Kite, and Tenant entered into that certain Consent to Assignment dated as of August 2, 2021 (“Consent”) wherein Landlord consented to the assignment of the Lease from Kite to Tenant since such assignment was not a Permitted Assignment.

C. Landlord and Tenant desire to amend the Lease, among other things, to extend the Base Term for a period of 34 months from the current expiration date of September 30, 2030 to July 31, 2033.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing Recitals, the mutual promises and conditions contained herein, and for other good and valuable consideration, the receipt and legal sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree that the Lease is amended as follows:

1. Definitions; Recitals. Terms used in this Sixth Amendment but not otherwise defined shall have the meanings set forth in the Lease. The Recitals form an integral part of this Sixth Amendment and are hereby incorporated by reference.

2. First Extension Term. The Base Term expires at midnight on September 30, 2030. The Base Term is hereby extended, such that it shall run for an additional period ("First Extension Term") beginning on October 1, 2030 and, unless earlier terminated or extended in accordance with the terms and conditions of the Lease, expiring 34 months thereafter (i.e., July 31, 2033). For purposes of the Lease, "Term" shall mean, collectively, the Base Term and the First Extension Term.
3. **Base Rent for First Extension Term**. During the First Extension Term, the Base Rent for the Premises shall be increased on each anniversary of the Adjustment Date (i.e., October 1 of each year), by multiplying the monthly Base Rent payable immediately before such Adjustment Date by the Rent Adjustment Percentage (i.e., [***%]) and adding the resulting amount to the monthly Base Rent payable immediately before such Adjustment Date, as set forth in Section 4 of the Lease. The Parties acknowledge that the first Adjustment Date after the Effective Date shall occur on October 1, 2021. Base Rent, as so adjusted, shall thereafter be due as provided in Section 4 of the Lease.

4. **Amendment to Basic Lease Provisions (Tenant’s Notice Address)**. Tenant’s Notice Address under the Lease is hereby changed to the following:

   **Tenant’s Notice Address:**
   
   [***]
   
   [***]
   
   [***]
   
   [***]

   - With copies via e-mail to:
     
     [***]
     
     [***]
     
     [***]

5. **Identification Signage**. Notwithstanding any contrary provision contained in Section 38(b) of the Lease, Tenant shall have the right to install and affix the Identification Signage on the façade of the Building facing Clopper Road subject to the terms and conditions as more fully set forth in Section 38(b) of the Lease.

6. [***]

7. **Roof Equipment**. Notwithstanding any contrary provision contained in Section 41 of the Lease, Tenant shall have the right (and, where applicable, the obligation) to install, maintain, and remove the Roof Equipment on the top of the roof the Building subject to the terms and conditions as more fully set forth in Section 41 of the Lease.

8. **Landlord Representations**. Landlord represents and warrants to Tenant that (i) the Lease, as amended by this Sixth Amendment, represents the entire agreement between Landlord and Tenant and there are no further or other instruments or agreements, written or verbal, between Landlord and Tenant regarding the lease of the Premises, (ii) Tenant is not in default pursuant to the terms of the Lease, and to Landlord’s Knowledge (as defined below), no event has occurred that, with the passage of time, or the giving of notice, or both, would constitute a default by Tenant under the Lease, (iii) both the Commencement Date and the Expansion Premises Commencement Date have occurred, (iv) [***]. For purposes of this paragraph, “Landlord’s Knowledge” means the current actual knowledge after reasonable inquiry of Lawrence J. Diamond, Co-Chief Operating Officer of Alexandria Real Estate Equities, Inc. In no event whatsoever shall Mr. Diamond have any personal liability under this Sixth Amendment.

   [***]

   [***]

a. This Sixth Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This Sixth Amendment may be amended only by an agreement in writing, signed by the parties hereto.

b. This Sixth Amendment is binding upon and shall inure to the benefit of the parties hereto, their respective agents, employees, representatives, officers, directors, divisions, subsidiaries, affiliates, assigns, heirs, successors in interest and shareholders.

c. This Sixth Amendment may be executed in 2 or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000), or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Sixth Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

d. Tenant and Landlord represents and warrants to the other that neither has dealt with any broker, agent, or other person (collectively, “Broker”) in connection with this Sixth Amendment and that no Broker brought about this transaction by or through the actions of such party. Landlord and Tenant hereby agrees to indemnify and hold each other harmless from and against any claims by any Broker claiming a commission or other form of compensation by virtue of having dealt with either Landlord or Tenant, respectively, with regard to this Sixth Amendment.

e. Except as amended and/or modified by this Sixth Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this Sixth Amendment. In the event of any conflict between the provisions of this Sixth Amendment and the provisions of the Lease, the provisions of this Sixth Amendment shall prevail. Regardless of whether specifically amended by this Sixth Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Sixth Amendment. All references in the Lease to the “Lease” shall be deemed to be a reference to the Lease as amended by this Sixth Amendment.
IN WITNESS WHEREOF, the parties hereto have executed this Sixth Amendment under seal as of the day and year first above written.

TELEFON PHIL.

BIONTECH US INC.,
a Delaware corporation

By: /s/ Richard Gaynor (SEAL)
Name: Richard Gaynor
Title: President

LANDLORD:

TECH PARK 270 III, LLC,
a Maryland limited liability company

By: ARE-MM Tech Park 270 III, LLC,
a Delaware limited liability company, managing member

By: ARE-930 Clopper Road, LLC,
a Delaware limited liability company, managing member

By: Alexandria Real Estate Equities, L.P.,
a Delaware limited partnership, managing member

By: ARE-QRS CORP.,
a Maryland corporation, general partner

By: __________________ ______ 
(SEAL)
Name: _______________________
Title: _________________________

Copyright © 2012. Alexandria Real Estate Equities, Inc. ALL RIGHTS RESERVED. Confidential and Proprietary. Do Not Copy or Distribute. Alexandria and Alexandria Logo are registered trademarks of Alexandria Real Estate Equities, Inc.
Side Letter No 5

to

LICENSE AND COLLABORATION AGREEMENT

by and between

BioNTech SE

and

Genmab A/S
This Side Letter No 5 is made and entered into as of 12th August 2021 (Side Letter No 5 Effective Date) by and between BioNTech SE, a German corporation having its principal office at An der Goldgrube 12, 55131 Mainz, Germany (BioNTech) and Genmab A/S, CVR no. 21023884, a Danish corporation having its principal office at Kalvebod Brygge 43, DK-1560 Copenhagen V, Denmark, (Genmab) (BioNTech and Genmab each a Party and together the Parties).

**PREAMBLE**

WHEREAS, the Parties entered into a License and Collaboration Agreement as of 19th May 2015, with subsequent amendments and side letters ("Agreement") under which the Parties collaborate with respect to research, development and commercialization of among others the Collaboration Products [***];

WHEREAS, the Parties would like to develop [***] and Genmab has entered into a certain [***] (said agreement is hereinafter referred to as the [***]) under which [***], ("[***]") would conduct certain work with such objective under specific Project Schedules (as defined below) executed under the [***];

WHEREAS, the Parties would inter alia like i) to clarify how ownership of intellectual property arising under the [***] will be treated under the Agreement and ii) to ensure that Genmab has the necessary rights to grant the licenses under the [***] to [***];

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements herein contained, and for good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree to the following:

1. Except as otherwise defined herein, the words and phrases in the Agreement shall have the same meaning in this Side Letter No 5.

2. **DEFINITIONS**

   [***]
   [***]
   [***]
3. Genmab has provided a copy of the executed version of the [***] to a limited group of representatives of Biontech under the [***] dated 6th January between [***], Biontech and Genmab US, Inc., subject to the letter agreement between Biontech and Genmab US, Inc. dated 4th June 2021. The [***] is hereby incorporated into this Side Letter No 5 by reference. Notwithstanding Section [***] of the [***], the Parties and [***] have agreed that any [***] IP generated under Project Schedule [***] shall be equally and jointly owned by
"[***]" Project Schedule "[***]" is hereby incorporated into this Side Letter No 5 by reference. In case Genmab and "[***]" negotiate an amendment to the "[***]" that relates to and/or affects a "[***]" Project Schedule that has been entered into in accordance with Section 4 below, Genmab shall involve Biontech in the process by (i) "[***]" and (ii) "[***]". Genmab and "[***]" shall not amend the "[***]" in a way that adversely affects Biontech's rights with respect to a "[***]" Project Schedule that has been entered into in accordance with Section 4 below, without obtaining Biontech's prior written consent, which can be provided via e-mail and which shall not be unreasonably withheld or delayed. The Parties acknowledge and agree that this Side Letter shall only apply to "[***]" collectively, "([***]" Project Schedules".

Genmab acknowledges and agree that the "[***]" Project Schedules are subject to the approval of Biontech in accordance with Section 4 below. Furthermore, Genmab acknowledges and agrees that it shall use commercially reasonable efforts to negotiate with "[***]" to secure that "[***]" IP generated under all future executed "[***]" Project Schedules shall be jointly and equally owned by "[***]".

4. Subject to the terms and conditions of this Side Letter No 5, Biontech hereby accepts and agrees

a) that Genmab may enter into the "[***]" Project Schedules under the "[***]" and that the terms of the "[***]" will be applicable to such "[***]" Project Schedules; provided, however, Genmab discloses the initial version of the relevant "[***]" Project Schedules (including the budget) to Biontech for review. Genmab shall continue to consult in good faith with Biontech throughout the negotiation of the "[***]" Project Schedules and shall not execute any "[***]" Project Schedules without Biontech's prior written consent, which can be provided via e-mail and which shall not be unreasonably withheld or delayed; and

b) that Genmab may enter into any Change Orders to any "[***]" Project Schedules and that the terms of the "[***]" will be applicable to such Change Orders, provided, however, Genmab discloses the initial version of the relevant Change Order (including changes to the budget, if any) to Biontech for review. Genmab shall continue to consult in good faith with Biontech throughout the negotiation of the relevant Change Order and shall not execute any Change Order to a "[***]" Project Schedule without Biontech's prior written consent, which can be provided via e-mail and which shall not be unreasonably withheld or delayed.
Biontech agrees to adhere to the terms of the [***] with respect to any subject matter covered by any [***] Project Schedule(s) (as amended by any Change Order(s)) that have been entered into in accordance with this Section 4. In case any work performed by Genmab under such [***] Project Schedule(s) or the fulfilment by Genmab of any of its obligations under such [***] Project Schedule(s) or the [***] requires a deviation from the terms of the Agreement, Biontech consents to the performance of such work or fulfilment by Genmab of such obligations, provided, however, that (i) Biontech is named third party beneficiary under the relevant [***] Project Schedule(s) pursuant to Section 21 below and (ii) that (A) [***] IP under Sections [***] of the [***] arising out of any work performed under the [***] Project Schedule(s) will, as between Biontech and Genmab, be treated as Program Inventions under the Agreement, always subject to Sections [***] of the [***] and subject to Section 9 below, and (B) [***] IP under Sections [***] of the [***] arising out of any work performed under the [***] Project Schedule(s) will, as between Biontech and Genmab, for all practical purposes be treated as Program Inventions under the Agreement, provided that Genmab shall [***] of such [***] IP with [***], and if set forth in the relevant [***] Project Schedule(s), Biontech, and always subject to Sections [***] of the [***] and subject to Section 10 below.

5. On Genmab’s reasonable request, Biontech shall without undue delay provide Genmab with reasonable assistance in connection with the performance of Genmab’s obligations under the [***] in relation to any [***] Project Schedule(s) entered into in accordance with Section 4 above (as amended by any Change Order(s)) in the event such assistance is reasonably required to comply with the [***] (including the relevant [***] Project Schedule(s)).

6. All and any costs (including but not limited to any termination costs) incurred by or on behalf of Genmab in relation to any [***] Project Schedule(s) (as amended by any Change Order(s)) that have been entered into in accordance with Section 4 above shall constitute [***] in accordance with the [***] mechanism under the Agreement. Any [***] incurred by Genmab under the [***] shall be borne solely by Genmab and shall not be considered [***] except to the extent that such [***] are a result of any breach by Biontech of any of its obligations pursuant to this Side Letter No 5 (including, for clarity, any in relation to any work performed on behalf of Genmab pursuant to a [***] Project Schedule).

7. Any [***] Intellectual Property is deemed to be comprised by the term ‘[***]’ when such term is used in the Agreement, including but not limited to Section [***] thereof.
8. Any [***] Intellectual Property is deemed to be comprised by the term [***] when such term is used in the Agreement, including but not limited to Section [***] thereof.

9. Genmab shall inform Biontech of any [***] IP generated under any [***] Project Schedule. To the extent such [***] IP is generated by [***] or its employees, agents or independent contractors, such information shall be made without undue delay upon Genmab’s receipt of [***] notification in accordance with Section [***] of the [***]. To the extent such [***] IP is generated by Genmab or its employees, agents or independent contractors, such information shall be made without undue delay upon Genmab’s notification to [***] in accordance with Section [***] of the [***]. All [***] IP including Intellectual Property thereto, which as between Genmab and [***] would be solely owned by Genmab under the [***] (cf. Section [***]) of the [***]) shall be deemed Program Inventions under the Agreement. With respect to any such Program Inventions that would constitute [***] IP and be jointly owned by the Parties pursuant to Section [***] of the Agreement, the Parties hereby agree that such [***] IP shall solely be used by the Parties within the scope of the Agreement.

10. Notwithstanding Section [***] of the [***], Genmab shall not be entitled to practice, exploit or license [***] IP, including Intellectual Property thereto, which as between Genmab and [***] would be jointly and equally owned by [***] under the [***] without the prior written consent of Biontech. If Biontech provides such written consent, Genmab hereby grants to Biontech a [***] sublicense [***] under its rights under Section [***] of the [***] within the scope of such consent. In the event a [***] Project Schedule that has been entered into in accordance with Section 4 above states that [***] IP generated under such executed [***] Project Schedule shall be jointly and equally owned by [***] and [***] under the [***], this Section 10 shall also be applicable to Biontech mutatis mutandis with respect to such [***] IP.

11. To the extent Biontech performs any part of any [***] on behalf of Genmab, Biontech hereby agrees that such work shall be subject to the terms of the [***], including but not limited to Sections [***] in the [***], and hereby assigns to Genmab any of its rights to any [***] IP to the extent required to enable Genmab to convey such rights to [***] as required in accordance with the terms and conditions of Section [***] in the [***]. For clarity, the costs incurred by or on behalf of Biontech for such work shall be [***] in accordance with the terms of the Agreement.

12. Notwithstanding any provisions to the contrary in the Agreement, Biontech hereby agrees that Genmab is entitled to grant to [***] a sublicense under the license according to Section [***] in the Agreement in order for [***] to perform its obligations or to exercise any of its rights under the relevant [***] Project Schedules (as amended by any Change Order(s)) that have been entered into in accordance with Section 4 above and the [***].
13. Notwithstanding any provisions to the contrary in the Agreement, [***] hereby agrees that [***] is entitled to grant to [***] a license under any [***] IP in order for [***] to perform its obligations or to exercise any of its rights under the relevant [***] Project Schedules (as amended by any Change Order(s)) that have been entered into in accordance with Section 4 above and the [***].

14. Notwithstanding Section 9 above and any provisions to the contrary in the Agreement, [***] hereby agrees that [***] may grant to [***] a) the license set forth in Section [***] of the [***] with respect to any [***] Intellectual Property and [***] IP and b) the license set forth in Section [***] of the [***] with respect to any [***] IP.

15. To the extent that any [***] would fall within the definition of [***] IP or the definition of [***] Intellectual Property and notwithstanding any provisions to the contrary in the Agreement, [***] hereby agrees that [***] is entitled to grant to [***] the licenses set forth in Sections [***] in the [***].

16. Under its license from [***] pursuant to Section [***] of the [***], and subject to the terms and conditions of the Agreement and the [***], Genmab hereby grants to Biontech a [***] license in [***] under [***] Intellectual Property and the [***] IP [***]), in accordance with the [***] and the relevant [***] Project Schedules(s) and shall, upon Biontech’s request, make available to Biontech such [***] Intellectual Property and [***] IP (e.g., any [***] included in such IP) to the extent required to enable Biontech to make use of the license granted in this Section 16.

17. The right to [***] IP as set forth in Section 9 above, the license granted in Section 16 above as well as any disclosures by Genmab to Biontech of [***] Confidential Information, Deliverables (as defined in the [***]) shall be subject to the non-use and confidentiality obligations and restrictions that apply to Genmab under the [***], including without limitation the obligations set forth in Section [***] of the [***]. Biontech hereby agrees to comply with all and any such obligations and restrictions that apply to Genmab under the [***] with respect to such right, license and disclosures.

18. Biontech agrees that Genmab may disclose any Confidential Information of Biontech to [***] under the relevant [***] Project Schedules (as amended by any Change Order(s)) to the extent [***] needs to know such Confidential Information in order to perform its obligations or to exercise any of its rights under the relevant [***] Project Schedules (as amended by any Change Order(s)) and the [***].
19. Genmab and Biontech shall agree on any material decisions to be made under any [***] Project Schedules in relation to 1) any Collaboration Product, 2) [***] Matters relating to any Collaboration Product, or 3) [***] Matters relating to any Collaboration Product (“Material Decisions”). For clarity, Material Decisions could include decisions on e.g. determination of [***] (as defined in the [***]), sourcing of [***] and [***] strategy, [***] strategy and [***] strategy for any Collaboration Product.

20. In case a Committee meeting will address one or more matter(s) that is/are relevant to any [***] Project Schedules (“Matter(s)”), Genmab shall ensure to invite a representative of Biontech to attend such Committee meeting solely with respect to such Matter(s). Without limiting the generality of Section 17 above, Biontech hereby agrees and shall ensure that any such representative shall be bound by the non-use and confidentiality obligations that apply to Genmab under the [***]. For clarity, any such representative shall have the right to participate in such Committee meeting but shall not have the right to vote on any Committee matters. Prior to any such Committee meeting, Genmab and Biontech shall agree on any Material Decisions that are to be taken with respect to the relevant Matter(s) during such Committee meeting and Genmab shall submit its vote on such Material Decisions in accordance with what has been agreed between Genmab and Biontech with respect to such Material Decisions.

21. A [***] Project Schedule that has been approved by Biontech in accordance with Section 4 above, may state that [***] and Genmab have agreed that Biontech is an intended third party beneficiary regarding Genmab’s ownership interests in, and Genmab’s rights to exploit, the [***] IP and [***] IP under Sections [***] of the [***] under Section [***] of the [***] with respect to [***] and related Intellectual Property arising pursuant to performance of such [***] Project Schedule (collectively, the “[***] IP Rights”). In such event, such third party designation of Biontech in such [***] Project Schedule reflects a desire of Genmab and Biontech to align their interests with respect to intellectual property rights and licenses as described in the [***]. Regarding Biontech’s intended third party beneficiary designation the following conditions will apply: (a) Biontech will not exercise its third party beneficiary rights (“3PB Rights”) unless Genmab fails to enforce any of the Genmab IP Rights that are within the scope of such 3PB Rights (taking reasonably into account Biontech’s interest as third party beneficiary); (b) if Genmab so fails to enforce any such [***] IP Rights, and if Biontech has reasonably determined that it wishes to exercise its 3PB Rights, then before exercising such 3PB Rights, Biontech must first notify Genmab in writing of such determination and its intended exercise, with a description of the [***] IP Rights that Genmab has failed to enforce; (c) before exercising Biontech’s right to enforce pursuant to its 3PB Rights, Genmab shall have [***] to enforce such described [***] IP Rights, or to provide to Biontech commercially reasonable reasons (taking reasonably into account Biontech’s interest as third party beneficiary) why Genmab has not undertaken such enforcement; and (d) only if Genmab (i) fails to so enforce, or (ii) has not provided commercially reasonable reasons for its decision not to enforce (taking reasonably into account Biontech’s interest as third party beneficiary), in each case of (i) and (ii), within such period pursuant to the foregoing clause (c), will Biontech be free to exercise its 3PB Rights, and only with respect to the
22. This Side Letter No 5 shall be governed by the same governing law as the Agreement, and all disputes arising out of or in connection with this Side Letter No 5 shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce as set forth in Section 17.10 of the Agreement.

23. The Parties agree that this Side Letter No 5 may be signed using a DocuSign® electronic signature. Such electronic signature is the legally binding equivalent to a Party’s handwritten signature and it has the same validity, enforceability and meaning as a handwritten signature and the Parties hereby waive any objection to the contrary.

IN WITNESS WHEREOF, the Parties hereto have caused this Side Letter No 5 to be executed and delivered as of the Side Letter No 5 Effective Date.

GENMAB A/S

By: [***]
Name: [***]
Title: [***]

BIONTECH SE

By: [***]
Name: [***]
Title: [***]
AMENDMENT NO. 1 TO COLLABORATION & LICENSE AGREEMENT

This Amendment No. 1 to the Collaboration & License Agreement ("Amendment") by and between The Trustees of the University of Pennsylvania, a Pennsylvania nonprofit corporation ("Penn"), with offices located at Penn Center for Innovation, 3600 Civic Center Blvd, 9th Floor, Philadelphia, PA 19104-4310, and BioNTech SE, a German corporation ("Sponsor"), having a place of business at An der Goldgrube 12, 55131 Mainz, Germany is effective September 8, 2021 ("Amendment Effective Date"). Penn and Sponsor may be referred to herein as a "Party" or, collectively, as "Parties".

RECITALS:

WHEREAS, the Parties entered into a Collaboration & License Agreement dated October 9, 2018 ("Agreement") under which the Parties are undertaking the development, manufacture and commercialization of mRNA vaccines for infectious diseases, including RNA synthesis, formulation and GMP manufacturing. Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Agreement;

WHEREAS, on January 4, 2021, BioNTech RNA Pharmaceuticals GmbH transferred all its assets to BioNTech SE with economic effect as of January 1, 2021, including the Agreement.

WHEREAS, Penn and BioNTech are now entering into this Amendment because Penn has conducted, at the request of BioNTech, translational research and IND enabling activities revolving around HSV-2 vaccine, and BioNTech desires that Penn conduct additional research and IND enabling activities related to the HSV-2 vaccine development program;

WHEREAS, the Parties want to reimburse Penn for translational research and IND enabling activities undertaken and align on research and IND enabling activities to be conducted at Penn revolving around the HSV-2 mRNA vaccine and future mRNA vaccines for infectious diseases under the Research Program; and

WHEREAS, the Parties now desire to amend the Agreement as set forth herein.

NOW, THEREFORE, in consideration of the various promises and undertakings set forth herein, the Parties agree as follows:

1. Scope of work and Budget. The Research Program detailed in Exhibit C to the Agreement and Initial Research Program Budget as set forth in Exhibit G to the Agreement are hereby amended to include the additional research plans and additional research budgets in Attachment A-1 hereto.

2. Funding of the Research Program. The following language shall be added to the end of Section 2.3.1 of the Agreement, “During the Research Term, Licensee shall provide additional funding to Penn to support additional research and IND enabling activities conducted at Penn as mutually agreed to under work plans described in Exhibits C-1 through C-8 (each an ‘Additional Research Plan’) and corresponding budgets in Exhibit G-1 through G-8 (each an ‘Additional Research Budget’). Future Additional Research Plans and Additional Research Budgets may be mutually agreed to and if executed by a duly authorized representative of each Party, such Additional Research Plans shall be added to the Agreement as Exhibit C-9, C-10, etc. and such associated Additional Research Budgets as Exhibits G-9, G-10, etc. Any Additional Research Budget shall be in addition to and shall not decrease, drawn down from, or otherwise impact the Research Funding Commitment.”
3. **Payment of Additional Research Budget.** Licensee shall pay Penn [***] US Dollars ($[***]) in accordance with the terms set forth in Exhibit G-1 to G-8, within [***] after invoice receipt.

4. **Entire Agreement of the Parties; Amendments.** The Agreement, including any Exhibits, as amended by this Amendment, constitutes and contains the entire understanding and agreement of the Parties with respect to the subject matter hereof and cancel and supersedes any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. No waiver, modification or amendment of any provision of the Agreement as amended and/or this Amendment shall be valid or effective unless made in a writing referencing the Agreement and/or this Amendment and signed by a duly authorized officer of each Party.

5. **Conflict.** Other than as set forth in this Amendment, all the terms and conditions of the Agreement shall continue in full force and effect. In the event of a conflict between the Agreement and the Amendment, the Amendment shall control.

6. **Counterparts.** This Amendment may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A portable document format (PDF) or electronic copy of this Amendment, including the signature pages, will be deemed an original.

[Signature Page Follows]
UNIVERSITY OF PENNSYLVANIA

IN WITNESS WHEREOF, the duly authorized representatives of the Parties hereby execute this Amendment as of the date first written above.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA

By: /s/ John S. Swartley
Name: John S. Swartley
Title: Managing Director

I have read and understood the responsibilities of the Designated Penn Contact:

By: /s/ Harvey Friedman, MD
Name: Harvey Friedman, MD

BIONTECH SE

By: /s/ Sierk Poetting
Name: Sierk Poetting
Title: Managing Director

I have read and understood the responsibilities of the Designated Penn Contact:

By: /s/ John S. Swartley
Name: John S. Swartley

Title: Managing Director

Title: Associate Vice Provost for Research, and Managing Director, Penn Center for Innovation
Additional Research Budget (Exhibits C-1 through C-7)

Exhibit C-1

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]
Exhibit C-2

***

***

***

***

***

***

***

***

***

***

***

***

***

***

***

***

Page 3
Transfer of Source Code for MyMUT® Software Version [***]

10.09.2021

TRON gGmbH is currently developing MyMut Software Version [***] and intends to successively transfer the full source code of the MyMUT® software version [***] latest by October 15th, 2021 under the URL [***], encrypted zip archive; the key will be sent separately as a printed copy to BioNTech. With regard to the use of the data and the software by BioNTech SE, TRON recognizes that the software will be used for the so-called IVAC project.

Since the IVAC Supplementary Agreement dated January 1st 2015 between TRON and BioNTech expired on December 31st 2019 and no other related agreement between BioNTech SE and TRON gGmbH has been concluded so far, TRON hereby transfers these data (including inventions, rights to patent applications/patents and so-called trade secrets) subject to the rights of use to which TRON, TRON AFFILIATED COMPANIES and the respective cooperation partners are entitled in the IVAC Supplementary Agreement with the proviso that Sec. 6.4.1. of the Framework Collaboration Agreement (“WP5”) between BioNTech SE and TRON gGmbH is applied as amended in Schedule 1, which amendment shall be effective solely for the purpose of this letter and the exploitation of the SOURCE CODE including any so called trade secret inventions contained in the SOURCE CODE. All other terms of the IVAC Supplementary Agreement shall remain unaffected. The parties further agree, via separate amendment, to extend the term of the IVAC Supplemental Agreement to Dec. 31st 2023.

BioNTech SE accepts transfer under this letter agreement and recognizes the fulfillment of the obligations by TRON according to the IVAC Supplementary Agreement with regard to the above data.

/s/ Michael Föhlings /s/ Dr. Andrée Rothermel /s/ Sierk Poetting
Managing Director Managing Director COO, Managing Director BioNTech

Bankverbindung: Mainzer Volksbank eG, IBAN: [***], BIC: [***]
Amtsgericht Mainz: HRB 43191 - USt.-Id.Nr.: DE 269156552

Michael Föhlings
Managing Director

Dr. Andrée Rothermel
Managing Director

Sierk Poetting
COO, Managing Director BioNTech
Schedule 1
Amendment to Sec. 6.4.1. of the Framework Collaboration Agreement ( "WP5")

This Amendment is agreed by the PARTIES for the sole purpose of regulating the remuneration payable by the relevant BIONTECH PARTY to TRON for the exploitation of a TRADE SECRET INVENTION to the extent any such TRADE SECRET INVENTION is part of the source code of the MyMUT® software version N under the URL [***] encrypted zip archive; the key will be sent separately as a printout (the "SOURCE CODE"). For this purpose only, Sec. 6.4.1 of the Framework Collaboration Agreement ("WP5") will read as follows:

"For the WP5 CONTRACTUAL PRODUCTS sold by it or its licensees (or sublicensees) to THIRD PARTIES which fall within the scope of protection of a VALID CLAIM of a WP5 PROJECT PATENT or a TRADE SECRET INVENTION, the BIONTECH PARTY shall pay TRON remuneration to the amount of:

(i) [***] percent ([***]) of the WP5 CONTRACTUAL PRODUCT’s NET SELLING PRICE up to an annual aggregate worldwide NET SELLING PRICE per WP5 CONTRACTUAL PRODUCT of [***] euro (€[***]); and
(ii) [***] percent ([***]) of the WP5 CONTRACTUAL PRODUCT’s NET SELLING PRICE if the annual aggregate worldwide NET SELLING PRICE per WP5 CONTRACTUAL PRODUCT exceeds [***] euro ([***])."

The aforementioned remuneration under this clause 6.4.1 shall be paid on a country-by-country basis for so long as the relevant WP5 CONTRACTUAL PRODUCT is covered by a VALID CLAIM of a WP5 PROJECT PATENT in the country of sale. If a WP5 CONTRACTUAL PRODUCT falls within the scope of a TRADE SECRET INVENTION, it is the mutual expectation of the PARTIES that the exploitation of such TRADE SECRET INVENTION will be coherent and jointly together with the exploitation of one or more WP5 PROJECT PATENTS.

Based on that understanding, the royalty pursuant to this clause 6.4.1 for the use of a TRADE SECRET INVENTION shall only be payable (x) if the relevant WP5 CONTRACTUAL PRODUCT also falls within the scope of protection of a VALID CLAIM of a WP5 PROJECT PATENT or, (y) in the event that the BIONTECH PARTY should exploit a TRADE SECRET INVENTION by entering into an agreement with a THIRD PARTY, if the relevant WP5 CONTRACTUAL PRODUCT also falls within the scope of protection of a VALID CLAIM of a patent (co)owned by such THIRD PARTY ("THIRD PARTY PATENT").

The royalty is payable, on a WP5 CONTRACTUAL PRODUCT-by-WP5 CONTRACTUAL PRODUCT basis, only once per WP5 CONTRACTUAL PRODUCT, even if a WP5 CONTRACTUAL PRODUCT falls within the scope of protection of several WP5 PROJECT PATENTS and/or TRADE SECRET INVENTIONS."

For the avoidance of doubt, the sentence in Sec. 6.4.1. of the Framework Collaboration Agreement ("WP5") starting “If such exploitation is undertaken…” shall be deleted in its entirety.

For all other purposes the original version of Sec. 6.4.1 shall remain unchanged, in full effect and shall not be affected by the aforementioned amendment.

TRON - Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH

Bankverbindung: Mainzer Volksbank eG, IBAN: [***], BIC: [***]
Amtsgericht Mainz: HRB 43191 - USt.-Id.Nr.: DE 269156552

[***]
This Amendment No. 2 to the Collaboration & License Agreement ("Amendment No. 2") by and between The Trustees of the University of Pennsylvania, a Pennsylvania nonprofit corporation ("Penn"), with offices located at Penn Center for Innovation, 3600 Civic Center Blvd, 9th Floor, Philadelphia, PA 19104-4310, and BioNTech SE, a German corporation ("Licensee"), having a place of business at An der Goldgrube 12, 55131 Mainz, Germany is effective December 22, 2021 ("Amendment No. 2 Effective Date"). Penn and Licensee may be referred to herein as a "Party" or, collectively, as "Parties".

RECITALS:

WHEREAS, the Parties entered into a Collaboration & License Agreement dated October 9, 2018, as previously amended on September 8, 2021, ("Agreement") under which the Parties are undertaking the development, manufacture and commercialization of mRNA vaccines for infectious diseases, including RNA synthesis, formulation and GMP manufacturing. Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Agreement;

WHEREAS, on January 4, 2021, BioNTech RNA Pharmaceuticals GmbH transferred all its assets to BioNTech SE with economic effect as of January 1, 2021, including the Agreement.

WHEREAS, the Parties are in active negotiation of a separate collaboration and license agreement ("Expanded Alliance Agreement") to, amongst other contemplated research and development programs, develop products based on certain additional Penn background patent rights ("Additional Penn Background Patents")

WHEREAS, Parties are now entering into this Amendment No. 2 because the Parties want to begin developing products based on the Additional Penn Background Patents commencing on the Amendment No. 2 Effective Date, while the Parties work diligently to complete their negotiation of the Expanded Alliance Agreement between the Parties;

WHEREAS, the Parties now desire to amend the Agreement as set forth herein.

NOW, THEREFORE, in consideration of the various promises and undertakings set forth herein, the Parties agree as follows:

1. Term of this Amendment No. 2. This Amendment No. 2 shall become effective on the Amendment No. 2 Effective Date and terminate upon the earlier of 1) six (6) months from the Amendment No. 2 Effective Date or 2) the effective date of the Expanded Alliance Agreement ("Amendment No. 2 Term"). Upon mutual agreement by the Parties, the Amendment No. 2 Term may be extended. At the end of the Amendment No. 2 Term, the Parties shall amend the Agreement to remove the Targeting Research Plan.

2. Scope of work. The Research Program detailed in Exhibit C to the Agreement ("Original Research Program") is hereby amended to include the additional research plans in Schedule A-1 hereto ("Targeting Research Plan") only during the Amendment No. 2 Term. Execution of this Amendment No. 2 does not obligate the Parties to enter into the Expanded Alliance Agreement. If the Amendment No. 2 Term ends upon the effective date of the Expanded Alliance Agreement, the Parties shall determine by mutual agreement if the Targeting Research Plan shall be moved to and included as a portion of the research program under the Expanded Alliance Agreement.
3. **Funding of the Research Program.** During the Amendment No. 2 Term, up to ($[***]) of the existing funding for the Original Research Program under the Agreement can be reallocated to fund the Targeting Research Plan upon mutual agreement of the Parties (“Targeting Research Plan Funding”). Penn represents that the Targeting Research Plan Funding shall not detrimentally impact any existing rights of Licensee under the Agreement. Any portion of the Targeting Research Plan Funding not used under this Amendment No. 2 shall be reallocated to the Original Research Program following termination of this Amendment No. 2. No further funding or payment by Licensee shall be required in connection with this Amendment No. 2, and the used portion of the Targeting Research Plan Funding will not be replenished by Licensee for the Original Research Program at the conclusion of the Amendment No. 2 Term.

4. **Additional Penn Background Patents.** The Additional Penn Background Patents means Penn’s rights and interest in the patents and patent applications specifically listed in Schedule B-1 hereto, together with any unlisted patents and patent applications claiming priority thereto, and any continuations, continuations-in-part (to the extent related directly to the subject matter of the parent application or containing new information developed pursuant to the Research Program), reissues, reexamination certificates, substitutions, divisionals, supplementary protection certificates, renewals, registrations, extensions including all confirmations, revalidations, patents of addition, PCTs, and pediatric exclusivity periods and all foreign counterparts thereof, and any patents issued or issuing with respect to any of the foregoing.

5. **Option to Additional Penn Background Patents.** Penn hereby grants to Licensee a time-limited option during the Amendment No. 2 Term and pursuant to or superseded by the terms of the Expanded Alliance Agreement to negotiate to acquire a commercial license to Additional Penn Background Patents Controlled by Penn to research, develop, make, have made, use, import, offer for sale, commercialize and sell products using or incorporating Additional Penn Background Patents in the APBP Field of Use (the “APBP Option”). For clarity, the APBP Option can only be exercised pursuant to the terms of and under the Expanded Alliance Agreement and shall automatically expire at the end of the Amendment No. 2 Term. “APBP Field of Use” means a) mRNA based diagnostics and therapeutics including mRNA based CAR-T and TCR therapies and b) lipid nanoparticle based mRNA delivery technologies, each for the diagnosis, detection, evaluation, prophylaxis and treatment of diseases in humans and animals, but specifically excluding the treatment and/or prevention of fibrosis in humans, including fibrosis caused by autoimmune disease and/or inflammation. “Controlled” means, with respect to intellectual property rights, that a Party or one of its Affiliates owns or has a license or sublicense to such intellectual property rights and has the ability to provide to, grant a license or sublicense to, or assign its right, title and interest in and to, such intellectual property rights as provided for in this Agreement without violating the terms of any agreement or other arrangement with any Third Party.

6. **Prosecution and Maintenance of Additional Penn Background Patents.** Additional Penn Background Patents will be held in the name of Penn. During the Amendment No. 2 Term, Penn shall have the sole and exclusive right to control the preparation, filing, prosecution and maintenance of the Additional Penn Background Patents. Patent expense reimbursement by Licensee for the APBP Option to the Additional Penn Background Patents shall be addressed in the Expanded Alliance Agreement.

7. **Entire Agreement of the Parties; Amendments.** The Agreement, including any Exhibits, as amended by this Amendment No. 2, constitutes and contains the entire understanding and agreement of the Parties with respect to the subject matter hereof and cancel and supersedes any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. No waiver, modification or amendment of any provision of the Agreement as amended and/or this Amendment No. 2 shall be valid or effective unless made in a writing referencing the Agreement and/or this Amendment No. 2 and signed by a duly authorized officer of each Party.
8. **Conflict.** Other than as set forth in this Amendment No. 2, all the terms and conditions of the Agreement shall continue in full force and effect. In the event of a conflict between the Agreement and the Amendment No. 2, the Amendment No. 2 shall control.

9. **Counterparts.** This Amendment No. 2 may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A portable document format (PDF) or electronic copy of this Amendment No. 2, including the signature pages, will be deemed an original.

---

[Signature Page Follows]
IN WITNESS WHEREOF, the duly authorized representatives of the Parties hereby execute this Amendment No. 2 as of the date first written above.

THE TRUSTEES OF THE
UNIVERSITY OF PENNSYLVANIA

By: /s/ John S. Swartley, Ph.D.
Name: John S. Swartley, Ph.D.
Title: Associate Vice Provost for Research and
Managing Director, Penn Center for Innovation

By: /s/ Jens Holstein
Name: Jens Holstein
Title: Managing Director

I have read and understood the responsibilities of the Designated Penn
Contact:

By: /s/ Dr. Drew Weissman
Name: Dr. Drew Weissman

UNIVERSITY OF PENNSYLVANIA

BIONTECH SE

By: /s/ Sean Marret
Name: Sean Marret
Title: Managing Director

By: /s/ Jens Holstein
Name: Jens Holstein
Title: Managing Director
Additional Research Plans

[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
Lease Agreement

for

Areas and Rooms in Building M536 and Building M537

at the Behringwerke site in Marburg

between

Pharmasset GmbH
Emil-von-Behring-Straße 76, 35041 Marburg, Germany

- hereinafter referred to as the “Lessor” -

and

BioNTech Manufacturing Marburg GmbH
Emil-von-Behring-Straße 76, 35041 Marburg, Germany

- hereinafter referred to as the “Lessee” -

Lessor and Lessee individually also referred to as the “Party”
or jointly as the “Parties”
The Lessee entered into the Lease Agreement for Buildings M537 and M536 (originally concluded between Pharmaserv GmbH & Co. KG and Chiron Behring GmbH & Co. KG) by way of a Takeover Agreement on July 1, 2021, 12:00 a.m. This Lease Agreement shall hereinafter be referred to as the “Old Agreement” and existed between Pharmaserv GmbH as the Lessor and GSK Vaccines GmbH as the Lessee before the takeover by the Lessee. The Old Agreement automatically ends on November 30, 2021, 12:00 a.m. the following day, according to the Takeover Agreement. The Parties have therefore agreed to reorganize the tenancy from December 1, 2021, 12:00 a.m., under this Lease Agreement.
Taking into account and continuing the aforementioned premises, the Parties agree as follows:

§ 1

Leased Property

(1) The 

Lessor, as owner, rents to the 

Lessee the areas and rooms marked in green in Appendix 1 within building M536 and building M537 at the location Behringwerke, Emil-von-Behring-Straße 76, 35041 Marburg, including the circulation and ancillary areas, insofar as these circulation and ancillary areas are marked “green” instead of “gray” in Appendix 1 (hereinafter referred to as the “Leased Property”).

The technical areas marked in blue may be used by the 

Lessee free of charge for the installation of the Lessee’s own technical equipment, depending on the space available.

The outer roof areas and facade areas and the outer parts of the building are not part of the lease. The 

Lessee is entitled to use these roof and facade areas free of charge in agreement with the 

Lessor, only to the extent that they are required for the realization of the purpose of the lease pursuant to § 2 of this Agreement.
The other parts of the building structure (for example, non-load-bearing walls), fixtures, fittings and equipment (also referred to in this Agreement as “Finishes”) located in building M536 and building M537 are leased to the Lessee and part of the Leased Property only to the extent that they are listed in Appendix 1 or listed as parts of the Leased Property in Appendix 2.1.

If and to the extent that internal parts of the building structure (for example walls), fixtures, fittings and equipment are present on the leased areas/rooms, the leased ancillary areas or circulation areas but are not listed in Appendix 1 or listed in Appendix 2.1, they are not part of the Leased Property, are therefore not owed by the Lessor and are only inserted into the buildings M537 and M536 for a temporary purpose (§95 of the German Civil Code [BGB]). These parts of the internal building structure, fixtures, fittings and equipment have been taken over by the Lessee from the previous tenants. Insofar as no takeover by the Lessee has taken place (for example, because it was not taken into account in corresponding transfer agreements among the previous tenants or with the Lessee or because it was ineffectively transferred), the right to use these parts of the internal building structure, fixtures, fittings and equipment is nevertheless not the subject of this Lease Agreement and is solely a matter between the Lessee and the previous tenants.

In particular, the lease does not include the Finishes that serve pharmaceutical purposes in the Leased Property which have been carried out in the Leased Property by the Lessee and the previous tenants, in particular by GSK Vaccines GmbH.

(2) In addition to Appendix 2.1, the condition of the Leased Property owed by the Lessor shall also result from Appendix 2.2 (building description of the Leased Property, equipment description of the Leased Property). The condition of the Leased Property set forth in Appendices 1), 2.1) and 2.2) shall merely constitute a description of the Leased Property and not a warranted characteristic.

The Lessee has possessed and used the Leased Property without interruption since July 1, 2021. The Lessee has not reported any defects.
The following special features are agreed upon with regard to the drainage pipe and wastewater system: drainage pipe (this is the wastewater pipe beginning at the inlet of the floor slab up to the first connection manhole in front of the building) including stormwater pipes (these are the pipes carrying the stormwater away from the roof up to the first connection manhole in front of the building) shall be made available for use, repaired and maintained, serviced and, if necessary, renewed by the Lessor for the duration of the lease in proper and functional condition in accordance with the following provisions, regardless of whether they are part of the Leased Property:

The drainage pipe extending from the floor slab/floor inlet (as shown in the section attached to Appendix 9 marked in red) to the connection to the wastewater disposal system of the Behringwerke Industrial Park shall be refurbished immediately and as soon as possible after the commencement of the lease at the expense of the Lessor in accordance with the refurbishment concept – Appendix 9 – even if this drainage pipe is not part of the Leased Property.

In addition, the wastewater pipes located in the building shall be refurbished by the Lessor at the Lessor’s expense without delay and as soon as possible after the commencement of the lease in accordance with Appendix 9 (insofar as they are part of the Leased Property (see Appendix 9)), whereby the wastewater pipes not required by the Lessee shall first be jointly identified, documented by addendum to this Lease Agreement and subsequently professionally plugged. After these pipes have been plugged, they are no longer part of the Leased Property. Claims for damages on the part of the Lessee due to possible damage to the drainage pipe and the stormwater pipes by the Lessor after the commencement of the lease shall remain unaffected by the assignment of duties to the Lessor made in accordance with § 17(3).

The Lessor shall be entitled to have existing technical building equipment in the Leased Property, insofar as it is part of the Leased Property, in particular fire protection and fault alarm systems, including the infrastructure required for it, to install it, convert and extend it, expand it and operate it and to renew it.
Purpose of the lease, orders, requirements, permits

(1) The Lessor shall provide the Leased Property to the Lessee for the purpose of carrying out pharmaceutical production, together with production-specific ancillary activities, within it with the inclusion of preexisting finishes, fixtures and equipment of the previous tenants and finishes to be carried out by the Lessee itself. The Lessor shall consent to any changes to the Leased Property itself that accompany the finishes made to the Leased Property unless good cause stands in the way of the Lessor’s consent. Good cause in the sense of this provision includes, in particular, effects of the planned changes on statics, fire protection, development, roof or facade of the Leased Property, additional costs threatening the Lessor as a result of the changes, or if the changes are opposed by provisions under public law.

Other uses, in particular the storage, handling or other transfer to the Leased Property of hazardous materials, explosives, foodstuffs, other perishable goods or objects from which a hazard may emanate or the storage, handling or other transfer of which require special structural conditions or equipment of the Leased Property or building which are not described in Appendices 2.1) and 2.2) or which are opposed by provisions of public law, are not included in the purpose of the lease.

If a special use within the agreed purpose of the lease requires special equipment (e.g. floor coverings or air-conditioning equipment) of the Leased Property that goes beyond the building and equipment descriptions pursuant to Appendices 2.1) and 2.2), it shall be the responsibility of the Lessee to provide such equipment at its own expense and to obtain the relevant permits. This shall apply accordingly in the event that changes are made to the Leased Property in the course of any finishes. In all other respects, § 11 (6) of this Lease Agreement shall apply.

(2) Official orders and requirements as well as necessary permits that are based exclusively on or required due to the general condition and/or location of the Leased Property shall be fulfilled or obtained by the Lessor at its own expense for the entire duration of the lease.
Insofar as official requirements and/or the obtaining/maintenance of official permits are caused by the personal or special operational circumstances of the Lessee or in the special circumstances of its business operations, the measures and costs associated therewith shall be the sole responsibility of the Lessee.

In this respect, the Lessee shall also comply with any official orders and requirements relating to the use of the Leased Property issued during the term of the lease at its own expense, even if they are directed against the Lessee. The Lessor shall provide the Lessee with the necessary and reasonable support in this regard.

(3) Any change of the purpose of use pursuant to subsection (1) above as well as changes of use of any kind requiring an official permit shall require the prior written consent of the Lessor.

The Lessee shall have no claim to such consent. Any declarations of consent by the Lessor shall always, even if this is not repeated in the declaration of consent, be subject to any required official permit, the procurement of which shall be the responsibility of the Lessee at its own expense. Prior to the implementation of the approved changes the Lessee shall demonstrate to the Lessor that either the official permit required for this purpose has been granted in a legally valid manner or that such a permit is not required, and shall comprehensively explain any disruptive impacts of the intended changed use.

(4) Insofar as official permits required for the use intended by the Lessee are not granted or are not granted to a sufficient extent, this shall not entitle the Lessee to terminate this lease, unless the cause thereof is a deviation of the actual condition of the Leased Property from the agreed condition of the Leased Property.
Regulations on value added tax

(1) In accordance with § 9 of the German Value Added Tax Act, the Lessor has waived the VAT exemption pursuant to § 4 (12) (a) of the German Value Added Tax Act (“UStG”) for the rental of the Leased Property (VAT option). As a result, the Lessee shall pay VAT in the respective statutory amount in addition to the rent, operating costs and advance payments for operating costs.

The Lessee is aware that the Lessor’s VAT option is only permissible under the conditions set out in § 9 (2) UStG.

Wording of § 9 (2) UStG for informational purposes:

“The waiver of tax exemption under subsection (1) is permissible in the case of the creation and transfer of heritable building rights (§ 4 (9) (a)), the renting or leasing of real estate (§ 4 (12) (1) (a)) and the transactions referred to in § 4 (12) (1) (b) and (c) only insofar as the recipient of the service uses or intends to use the real estate exclusively for transactions that do not exclude the deduction of input tax. The entrepreneur must provide evidence of these conditions.”

In view of this, the Parties enter into the following agreements:

(2) The Lessee agrees to use the Leased Property exclusively for transactions which do not exclude the deduction of input tax by the Lessor.

(3) Furthermore, the Lessee agrees to provide the Lessor at any time, upon request and without delay, with the documents required to enable the Lessor to comply with its obligations to provide evidence to the tax authorities pursuant to § 9 (2) UStG. In this respect, the Lessor may only require the Lessee to submit those documents and/or declarations that are required of it by the responsible tax authorities. The Lessee shall be entitled to forward the requested documents directly to the tax authorities.

(4) Should circumstances arise on the part of the Lessee or a subtenant, or be assumed by the tax authorities in the course of an external tax audit, which affect the permissibility of the Lessor’s VAT option, the Lessee shall be obliged to inform the Lessor thereof in written form without delay.
In the event of a sublease, the Lessee shall be obligated to opt for VAT for the sublease and otherwise to impose the obligations under § 3 (2) to (5) of this Lease Agreement on the subtenant in the sublease agreement in such a way that the Lessee may also derive rights directly against the subtenant under the agreement of the Lessee with the subtenant (agreement in favor of third parties, § 328 of the German Civil Code [BGB]). The Lessee shall be liable to the Lessor for ensuring that the subtenant complies with these obligations.

Insofar and as long as the tax authorities apply a de minimis limitation with no detrimental effect – also recognized by the tax courts – with regard to the term “exclusive” use for transactions which do not exclude the deduction of input tax, this de minimis limit shall at the same time limit the exclusivity referred to in the above provisions.

Should the Lessee and/or, in the event of a sublease, the subtenant violate the obligations under § 3 (2) to (6) of this Lease Agreement, the Lessee shall compensate the Lessor for all damages and other disadvantages caused thereby.

If the precondition for the Lessor’s VAT option under § 3 (1) of this Lease Agreement no longer applies because the Lessee does not use the Leased Property in accordance with the agreement made in § 3 (2) of this Lease Agreement, the Lessor shall no longer be obliged to list VAT separately. In this case, the net base rent owed under this Lease Agreement – without prejudice to any further rights and/or claims of the Lessor – shall be increased as of the date on which the precondition for the VAT option ceased to apply by the amount corresponding to the VAT that would have been payable by the Lessee if the precondition for the VAT option had not ceased to apply. If the Lessor only becomes aware of the absence of the precondition for the VAT option after the fact, the Lessor shall be entitled to correct the invoices issued to date in such a way that the invoiced rent with VAT shown corresponds to the contractually owed rent without VAT shown. Further claims of the Lessor based on a breach of contract by the Lessee shall remain unaffected.
Claims of the Lessor against the Lessee under § 3 shall become time-barred upon expiration of ten years after termination of the lease. Should the Lessee or the subtenant fail to comply with its duty to provide information pursuant to § 3 (4), the limitation period shall be extended to 15 years for all claims based on circumstances of which the Lessor has not been informed by the Lessee or subtenant in breach of its duty.

§ 4

Lease term

(3) Tacit extension of the lease pursuant to § 545 BGB is excluded.

Page 10 of 32
§ 5

Uninterrupted possession of the Leased Property, keys

(1) The Lessee is already in possession of the Leased Property. The Parties confirm that the Lessee's possession will be maintained uninterrupted.

(2) The Lessee is also in possession of the necessary keys. With the consent of the Lessor, it is entitled to produce additional keys at its own expense.

All keys shall be handed over by the Lessee to the Lessor after the end of the lease. The Lessor is entitled, in consultation with the Lessor, to install and operate its own locking system for its leased areas at its own expense or to change and expand an existing locking system. The Lessee shall provide the Lessor with access to the leased areas and rooms for the cases agreed in this Lease Agreement. When moving out, the Lessee must restore the Lessor's locking system to its original condition where possible or provide the changed or extended locking system to the Lessor, whereby the Lessee shall not be entitled to compensation in this case.

§ 6

Rent

(1) The monthly net base rent (graduated rent) also for the option periods is fixed in Appendix 4) by the Parties and is the result of extensive negotiations between the Lessor and Lessee. A significant reduction in rent was included in these negotiations, as well as the now agreed definition of the Leased Property and the corresponding allocation of maintenance and repair obligations.

(2) With regard to the net base rent and with regard to all operating costs pursuant to § 8, the Lessee shall also pay VAT at the respective statutory rate, i.e. currently 19%.
The monthly rent, including the advance payment of operating costs pursuant to § 8, shall be paid to the Lessor in advance, free of charge, no later than on the [***] working day of each month to the account at Volksbank Mittelhessen eG. [***] with the reference [***].

(4) The Lessee shall only be entitled to set off against payment claims of the Lessor and to exercise a right of retention if its counterclaims are acknowledged or have become established by a final judgment.

§ 7

Rent adjustment

The monthly net base rent shall increase on January 1 of each year by [***] compared to the previous year. This annual increase is already taken into account in the statement of rent in Appendix 4 of the Lease Agreement.

§ 8

Operating costs

(1) The Lessee shall bear all operating costs in addition to the net base rent. Operating costs are the costs incurred by the Lessor on an ongoing basis as a result of ownership of the property or as a result of the intended use of the Leased Property, the building or the management unit, its facilities and equipment and the land. The operating costs to be borne by the Lessee currently include those pursuant to Appendix 5.1) to this Lease Agreement. The operating costs to be borne by the Lessee also include the operating costs incurred by the Lessor on an ongoing basis as a result of the operation of the Behringwerke site and referred to as “Basic Infrastructure Costs” in Appendix 5.3.

(2) If public assessments are newly introduced or if new operating costs within the meaning of this Lease Agreement are incurred by the Lessor as a result of the fulfillment of statutory obligations with respect to the Leased Property that have arisen after the conclusion of this Lease Agreement, such costs may be apportioned in accordance with this Lease Agreement, and the advance payment of operating costs may be adjusted accordingly. The adjustment of operating costs specified in Appendix 5.1) as well as the establishment of new operating costs which do not relate to public assessments or the fulfillment of statutory obligations arising after the conclusion of the Lease Agreement with respect to the Leased Property may only be made taking into account the principle of sound financial management. The Lessor shall inform the Lessee of the operating costs without delay.
3. Insofar as the Lessor provides services in its own business operations which, in the case of their provision by third parties would have to be borne as part of the operating costs in accordance with this Lease Agreement, the Lessor may charge for such services at an amount which corresponds to appropriate remuneration plus, if applicable, the VAT in force at the time of performance for these services (e.g., if agreed, supply of energy and media to the location at the respective prices, elevator maintenance).

4. Unless mandatory provisions to the contrary apply, the operating costs shall be apportioned in accordance with the share of the total area of the building attributable to the Lessee. The settlement period shall be the calendar year. The ratio between the Lessee’s share of the area and the total area of Building M536 and Building M537 agreed only for the purpose of allocating the operating costs is bindingly agreed by the Parties in Appendix 3 to this Lease Agreement.

5. The Lessor may change the apportionment scale with future effect in agreement with the Lessee at its reasonable discretion.

6. The operating costs referred to as “Basic Infrastructure Costs” in Appendix 5.1 shall be determined in accordance with the agreement made in Appendix 5.1 for the settlement year and shall be apportioned to the Lessee in accordance with the procedures agreed in Appendix 5.1. The Basic Infrastructure Costs shall not be subject to the monthly advance payment of operating costs (Appendix 5.2), but shall be invoiced separately by the Lessor and reimbursed by the Lessee.

7. Insofar as fire protection and fault alarm systems and other technical building equipment required for the operation of the building – with the exception of access control equipment – is located in areas shared with other tenants of Building M536 and/or Building M537 and/or other buildings, these buildings shall form the settlement unit for these types of costs. The tenants shall bear the costs of these facilities in proportion to the areas used exclusively by each of them to the total area of the settlement units M536 and M537 (Appendix 3). The same applies to lightning protection.
8. The Lessee shall make monthly advance payments for the operating costs which, insofar as these are not the operating costs designated as “Basic Infrastructure Costs,” shall be determined as follows:

For each calendar year, the Lessor shall estimate in advance a budgeted amount of the operating costs and shall invoice the Lessee 1/12 plus VAT of this amount as an advance operating cost payment in advance on a monthly basis.

9. After the end of the settlement period (calendar year), the Lessor shall determine all operating costs incurred during the settlement period as part of the statement of operating costs. The Lessor shall compare the operating costs actually incurred with the advance operating cost payments made by the Lessee and shall notify the Lessee of the result by way of the statement of operating costs.

10. Any difference between the advance payment amount and the settlement amount in favor of the Lessor/Lessee shall be settled by the Lessor/Lessee within [***] months after receipt of the statement of account by the Lessee plus the VAT applicable at the time of performance.

11. Objections to the statement of account must be asserted by the Lessee in writing with the Lessor within [***] months of receipt thereof. Otherwise, any objections to the correctness of the statement of account shall be excluded, unless the Lessor is not responsible for the delayed assertion, or the Lessor has not expressly pointed out this exclusion period and the consequences of its expiration in the statement of account. The Lessor shall allow the Lessee to inspect the accounting documents at the Lessor’s business premises during normal business hours at the Lessee’s request and after prior agreement on a date within [***] months after receipt of the statement of account.
In the event that the Lessee moves out during the settlement period, the apportionment at the next invoice due shall, in case of doubt, be in the ratio of the lease period to the settlement period.

The advance payment amounts current at the commencement of the Agreement are attached to this Agreement as Appendix 5.2. The Parties agree that Appendix 5.2 shall not be amended and a new Appendix shall not be added to the Agreement in case of a change of the advance payment amounts, but that a mere notification of the change (e.g. in the form of an invoice) by the Lessor shall be sufficient.

The Lessor shall provide the Lessee with the statement of account no later than the end of the [***] month after the end of the settlement period, after it has received all the documents and information required for the preparation of the statement of operating costs. After expiration of this period (these periods), the assertion of any subsequent claims by the Lessor shall be excluded, unless the Lessor is not responsible for the late assertion.

§ 9
Operator responsibility, liability of the Lessee

(1) The Lessee shall, at its own expense, create all the conditions for the legally compliant operation of its business in conformity with the law (operator responsibility).

The Lessee shall comply with any requirements imposed by the trade supervisory authority or other bodies at its own expense, insofar as such requirements are specifically related to the Lessee’s business or its activities in the Leased Property, even if they are directed against the Lessor. § 2 (2) of this Lease Agreement shall remain unaffected.

The Lessee shall conduct its business in the Leased Property in accordance with the applicable statutory regulations and in accordance with the requirements of national and international authorities.
(2) The Lessee shall indemnify the Lessor against all claims asserted by third parties on account of the Lessee’s operator responsibility vis-à-vis the Lessor. § 15 (1) of this Agreement shall remain unaffected.

(3) The Lessee shall be responsible for any culpable damage to the Leased Property and the building as well as to all facilities and equipment belonging to the building or the premises if and to the extent that the damage was caused by the Lessee or its bodies, employees, subtenants, visitors, suppliers or service providers commissioned by the Lessee, if such persons gained access to the building at the Lessee’s instigation or with its approval. The Lessor shall be responsible for proving that there was no fault or negligence on its part insofar as damage to the Leased Property is concerned.

(4) If, due to blockage, the leaving open of water taps or similar events, a flood or other damage to the building, objects or third parties, the Lessor shall, insofar as the event was caused in the Leased Property, be responsible for the repair of the damage and the elimination of all consequential damage resulting therefrom. This shall not apply if the damage is attributable to the Lessor or third parties who have entered the Leased Property at the Lessor’s instigation or with its approval.

(5) Claims for compensation by the Lessor pursuant to § 548 (1) BGB due to contamination of the Leased Property or the building caused by the Lessee or its subtenants or other persons entering or driving onto the Leased Property with the knowledge of the Lessee shall become statute-barred 18 months after the return of the Leased Property. Contamination in the sense of this clause refers to harmful environmental effects and pollution of the soil, buildings, parts of buildings, paved outdoor facilities or groundwater. Contamination in this sense refers, in particular, also to harmful changes to the soil and contaminated sites within the meaning of § 2 (3) and (5) of the German Federal Soil Protection Act (BBodSchG).
(1) The Lessee is aware that the Leased Property is located on the premises of an industrial park and that the use of the Leased Property may be impaired in a manner customary for an industrial park, for example by emissions from neighboring users or by work on supply lines, roads and neighboring buildings and properties.

(2) The Lessor’s strict liability for damages for initial defects is excluded.

(3) If the Lessor defaults in remedying the defect, the Lessee may remedy the defect itself and demand reimbursement of the expenses required for this purpose.

(4) The Lessee shall only be entitled to a rent reduction under the condition that a reasonable period of time set by the Lessee for the Lessor to remedy the defect has elapsed unused.

(5) Claims for damages by the Lessee, unless excluded under this Agreement, including those arising from pre-contractual obligations and tort, may only be asserted if the Lessor has acted culpably. In the event of a breach of non-essential contractual obligations, however, such claims may only be asserted if they are based on intent or gross negligence on the part of the Lessor or its vicarious agents. Material contractual obligations (cardinal obligations) are obligations the fulfillment of which makes the proper execution of the Agreement possible in the first place and the observance of which the Party to the Agreement regularly relies on and may rely on. The Lessor’s liability for damages shall be limited to foreseeable, typical damage. If the Lessor has covered the above typical risk of damage with insurance, liability for damages shall be limited to the sum insured, unless the insurer can invoke its exemption from performance in whole or in part. The sum insured shall at least correspond to the requirements pursuant to § 14 (1).
§ 11
Maintenance, repair and cosmetic repairs, structural and technical modifications

(1) In accordance with the negotiations held on November 23, 2021, the Lessor shall only be responsible for the maintenance (including servicing and inspection) and repair of the Leased Property within the limits of its definition pursuant to § 1 of the Lease Agreement, i.e. of the roof and framework (only to the extent described in Appendix 1 and Appendix 2.1), the building shell and the load-bearing components (including windows and exterior doors) and the fixtures, fittings and equipment of the Leased Property described in Appendices 2.1 and 2.2, as well as the drainpipes and stormwater pipes pursuant to § 1 (3) of this Agreement, as well as to maintain and repair the circulation and ancillary areas (marked “gray” in Appendix 1) and other common technical facilities, installations and areas, including the common area. Major maintenance and repair work to be carried out by the Lessor, i.e. such work as may have a significant effect on the Lessee’s operations, shall be coordinated between the Lessor and the Lessee well in advance. Prior coordination is not required if there is an imminent danger.

(2) In accordance with the statements in the preliminary remarks of this Lease Agreement, the Lessee shall be entitled at its own expense for the maintenance (including servicing and inspection) and repair of the technical facilities and equipment existing in or on Buildings 536 and 537, as far as these are not listed in Appendices 2.1 and 2.2 as part of the Leased Property, and shall only be obligated to maintain and repair the same if not as
such obligation arises from the operator responsibility pursuant to § 9 of this Lease Agreement or a risk to the Leased Property or personal injury cannot be ruled out. In particular, all work required by law and/or necessary according to the manufacturer’s specifications to maintain the operational readiness and operational safety of these fittings, facilities and equipment shall be carried out by the Lessee at its expense. The same shall apply in particular to the maintenance (including servicing and inspection) and repair of the installations and conversions, fixtures and equipment carried out by the previous tenants and by the Lessee itself.

(3) Cosmetic repairs are to be carried out neither by the Lessor nor by the Lessee.

(4) The Lessor shall give the Lessee written notice of any modernization measures (§ 555 c BGB) to be carried out in the Leased Property with a reasonable period of notice prior to commencement of such measures in the Leased Property. As a rule, the Parties consider a period of three months to be reasonable. The Lessee’s special right of termination in the event of modernization measures (§ 555e (1) BGB) is excluded by mutual agreement.

(5) The Lessee shall treat with care the sanitary facilities, locks, lighting fixtures, built-in furniture, kitchens, external blinds and thermostats provided by the Lessor, insofar as these exist. Defective light bulbs shall be replaced by the Lessee. The Lessee shall keep the Leased Property free of vermin at its own expense and maintain sanitary facilities and social spaces, insofar as they exist in the Leased Property, in a proper, in particular hygienic, condition at all times and shall clean the leased areas used only by itself (excluding common areas) regularly and shall properly clean the windows at least twice a year.

(6) With the exception of the extension of the Leased Property permitted within the scope of the purpose of the lease pursuant to § 2 (1) of this Lease Agreement, the Lessee shall be entitled to make structural and/or technical changes to the Leased Property as defined in § 1 of this Lease Agreement itself only with the prior consent of the Lessor, to which the Lessee shall have no claim. To obtain consent on the part of the
Lessor, the Lessee must submit a detailed description of the planned structural change, including all relevant descriptions, a planning diagram and a presentation of the effects of the structural change in terms of permit requirements, insurance requirements, any disruptive environmental impacts such as noise or other emissions and the functioning of the building as a whole. Any declarations of consent by the Lessor shall always be issued, even if this is not repeated in the declaration of consent, subject to any necessary official approval, the procurement of which shall be the responsibility of the Lessee at its own expense. The Lessee shall be liable to the Lessor regardless of fault for any damage occurring during or as a result of the structural change, including effects on other leased areas, and for compliance with building regulations, and shall indemnify the Lessor in full in this respect. This shall also apply if defects or other impairments of the Leased Property or other leased units occur as a result of the structural change. The costs of any structural change, including all planning and permit costs, shall be borne by the Lessee.

All construction and/or technical changes to be made by the Lessee, insofar as they affect the Leased Property itself, must be sufficiently documented in writing, including the type and scope of the changes, prior to implementation of the measure by way of supplementary management.

§ 12

Company signs

(1) The Lessee may, taking into account the circumstances at the site and after consultation with the Lessor, affix its company name itself at its own expense only on those buildings of which it is the sole user. It shall bear the costs for affixing these signs. If official permits are required for the affixing of these signs, the Lessor shall obtain them and bear the costs incurred thereby. The Lessee shall be responsible for ensuring the safety of the fixtures which it attaches.

(2) The type, size and location of (display) boxes or boards for internal communication and information that are installed outside the areas used exclusively by the Lessee shall also be coordinated between the Lessee and the Lessor.
3. If the removal of the company signs pursuant to subsections (1) or (2) is necessary for work on the site or on the Leased Property, the Lessee shall bear the costs of the removal, storage and reattachment, including any repairs to the fixture necessitated thereby. Upon termination of the lease, the Lessee shall remove the company signs at its own expense and remove at its own expense any damage caused by attaching, operating and removing them.

4. If the Lessor erects uniform company signs, the Lessee shall share appropriately in the costs of erecting and maintaining such signs.

§ 13

Technical building equipment, supply and disposal

1. The Leased Property shall have a technical connection for the supply of electrical power, drinking water and data communication to the currently existing supply and disposal facilities of the site. The Lessee shall itself and at its own expense ensure the supply of the Leased Property with the energy and media required for its use by concluding separate energy supply contracts with the Lessor or with third parties. The Lessee shall itself provide for the adequate heating of the Leased Property. If increased connection capacities or connections for other energy or media are required in addition to the connection available at the commencement of the lease, the Parties shall enter into discussions on this matter; the Lessee shall have no claim to the establishment of increased connection capacities or further connections.

Wastewater disposal is not the subject of this Lease Agreement and is therefore not owed by the Lessor under this Lease Agreement, but is governed by the Wastewater Agreement between the Lessor and the Lessee dated March 25/April 12, 2021 (Appendix 8), as amended.

2. The Lessee shall use the supply and disposal lines installed in the Leased Property, e.g. for electricity, gas, nitrogen, compressed air and water/wastewater, only to the extent that no overloads occur.
The Lessee may cover any additional demand by extending the lines and necessary technical equipment at its own expense after prior written consent of the Lessor, which may only be refused for good cause.

(3) If, as a result of a legally mandatory conversion of a type of energy supply, it is necessary to convert equipment or installations, parts of installations and ancillary equipment belonging to the Lessee, the costs of converting these equipment and installations, parts of installations and ancillary equipment shall be borne by the Lessee. Any claims for compensation on the part of the Lessor as well as claims for a reduction of the rent shall be excluded in this case.

(4) Prior to setting up shelves, heavy machinery, apparatuses and safes in the Leased Property, the Lessee shall inquire with the Lessor about the permissible load limits of the floor and the floor ceilings and obtain the Lessor’s prior written consent. The Lessor shall be liable for any damage caused by non-compliance with these provisions; any liability on the part of the Lessee shall be excluded. If machinery causes disturbances or other detrimental effects on the building, vibrations, cracks, etc., the Lessor may revoke the permission granted or impose subsequent conditions. The Lessor shall also not be liable for the suitability of the Leased Property for the installation or connection of equipment.

§ 14
Insurance

(1) From the time of handover, the Lessor shall maintain all-risk property insurance, including fire insurance for the building, as well as liability insurance with a minimum coverage of €10 million. The costs of these insurance policies form – if applicable, on a pro rata basis – part of the operating costs pursuant to § 8 of this Agreement.

(2) The Lessee shall be obliged to take out, at its own expense, liability insurance providing coverage for damage to rented property with a minimum sum insured of €10 million from the commencement of the lease, as well as all insurance policies required for operation pursuant to § 2 of this Agreement. Global insurance policies or policies that provide for a deductible on the part of the Lessee fulfill this requirement.
In the event of an increase in the insured risk, the Lessee shall extend its insurance coverage without being requested to do so.

(3) All insurance policies shall be maintained during the term of the lease, either through a continuation of the respective insurance policy or by taking out new comparable insurance policies. The sole decisive factor is that insurance coverage must exist for the entire term.

(4) Upon request of the other Party, each Party shall submit certificates of the insurance policies it is required to take out, showing the amount of the deductible, and shall provide proof of premium payment on request at any time.

(5) Each Party agrees to draw the other Party’s attention without delay to any lacking or insufficient general or special insurance coverage which it has identified. This shall apply in particular to circumstances which have or may have the effect of changing or increasing the risk, in particular in the case of installations, structural measures or changes of use.

(6) The Lessee shall notify the insurer and the Lessor immediately of any case of damage and shall ensure that the site of the damage – wherever possible and reasonable – remains unchanged prior to inspection by the insurer. Notwithstanding the foregoing, the Parties shall be obligated to take such measures as are necessary to mitigate the damage or to reduce consequential damages. The Parties shall carry out these measures in coordination with each other and with the respective insurer.

§ 15
Termination of the lease, obligation to surrender, restoration of the original condition

(1) Upon termination of the lease, the Lessee shall return the Leased Property in accordance with the provisions of this Agreement and otherwise in a broom-clean condition and free of substances that are likely to cause hazards, significant disadvantages or significant nuisances within the meaning of § 3 of the German Federal Emissions Control Act for individuals or the general public (hereinafter collectively referred to as “Contamination”), insofar as they were caused by the Lessee.
If there is Contamination of the Leased Property or of fixtures, fittings and equipment that are not part of the lease, the Lessee shall indemnify the Lessor in full, even during the term of the lease, if a claim is made against the Lessor for investigation, remediation or other measures relating to the Contamination, as well as against any claims by third parties in connection with such Contamination. However, this shall only apply insofar as the Lessor proves that the contamination of the Leased Property was caused by the Lessee after the commencement of this contractual relationship. This proof of causation by the Lessor shall not be required with respect to the fixtures, fittings and equipment that are not part of the lease, in particular those taken over by the Lessee from the previous tenants.

(2) In accordance with the statements in the preliminary remarks of this Lease Agreement, the Lessee shall be obligated upon termination of the lease to

- to remove all fittings, installations and equipment located in the Leased Property, unless these are identified as part of the Leased Property in Appendices 2.1) and 2.2) to the Lease Agreement, including their connections to the Leased Property, in a professional manner at its own expense, even if these fittings, installations and equipment were not introduced to the Leased Property by the Lessee and regardless of whether this was done before or during the lease established by this Lease Agreement. The Parties clarify that the underground pipes as defined in § 1 (3) of this Lease Agreement and stormwater pipes may remain in the Leased Property.
- to restore the Leased Property to the structural condition as set forth in Appendix 1) and Appendices 2.1) and 2.2), even if the structural or technical changes have not been made by the Lessee and regardless of whether this was done before or during the lease established by this Lease Agreement; and
- to remove its movable inventory at its own expense unless the Lessor has waived this in writing in an addendum to this Lease Agreement.
(4) If the Lessee fails to comply with its obligation to return the Leased Property in due time pursuant to subsection (1), it shall pay to the Lessor, on the basis of a daily settlement per day of the delayed return, 1/30 of the last monthly net base rent paid, plus 1/30 of the last monthly advance payment of operating costs paid, plus the statutory VAT applicable at the time of performance. The assertion of further damages by the Lessor remains reserved.

(5) The Parties shall prepare a written handover report on the return of the Leased Property.

(6) The Lessor agrees to reimburse the Lessee in the event that the Lease Agreement is terminated at the end of December 31, 2031 for the documented costs for measures pursuant to § 15 (2) of this Lease Agreement up to an amount of € [***] (in words: [***] euros) (“Reimbursement Amount”). In the event that the Lease Agreement is terminated at the end of December 31, 2036 or at the end of December 31, 2041, the maximum Reimbursement Amount in both cases shall be € [***] (in words: [***] euros).

§ 16
Force majeure

Insofar and as long as a Party is prevented from fulfilling its contractual obligations for reasons of force majeure, it shall be released from such fulfillment. It shall immediately notify the other Party of the circumstances of force majeure and endeavor to remedy such circumstances. To the extent necessary and possible, the Parties shall agree on necessary adjustment measures. The Parties clarify that force majeure shall be understood to mean an extraordinary event of external origin, unforeseeable and uncontrollable, which cannot be prevented or averted even by the utmost care, e.g. lightning, earthquake, war, warlike conditions, floods etc.
§ 17 Confidentiality

(1) The Parties mutually agree to keep confidential any information they receive in connection with the conclusion of this Lease Agreement and its performance, including the economic framework conditions and the provisions of this Lease Agreement as well as any business and trade secrets that may become known. This means that corresponding information may not be disclosed to third parties without the prior written consent of the other Party.

Excluded from this is the disclosure of information to third parties engaged by one Party for the performance of the Agreement, but only to the extent that it is absolutely necessary for such performance.

However, it is a prerequisite that such third parties (e.g. lawyers, tax consultants, brokers, experts, tradespeople etc.) are in turn obliged to maintain confidentiality.

The above duty of confidentiality shall apply for a period of up to [***] years after termination of the lease.

(2) Excluded from the duty of confidentiality pursuant to subsection (1) shall be such information which the Parties have already received prior to the conclusion of the lease, regardless of its performance, or such information which may be obtained by one of the Parties from generally accessible sources without either of the Parties having brought this about by violating the duty of confidentiality.

The duty of confidentiality shall not apply if one of the Parties discloses the information necessary for this purpose on the basis of a statutory or official order or in legal proceedings in order to safeguard its legitimate interests.
§ 18
Collateral

(1) In order to secure all claims of the Lessor against the Lessee arising from this Lease Agreement, the Lessee shall, within 2 months of signing this Agreement, provide on first demand a directly enforceable guarantee of a bank licensed to do business in accordance with the attached sample (Appendix 7) for an amount corresponding to 3 times the monthly base rent at the beginning of the lease, plus advance payment of operating costs at the beginning of the lease, plus VAT.

(2) If the Lessee fails to provide a proper lease guarantee within the agreed period, after setting a reasonable grace period, the Lessor shall be entitled to terminate the lease without notice for good cause.

(3) The guarantee shall be returned by the Lessor to the Lessee at the end of 6 months after the termination of the lease, unless the Lessor asserts claims from the lease secured by the guarantee against the Lessee or the guarantor.

§ 19
Subletting, transfer of use and partial transfer

(1) The Lessee shall only be entitled to transfer the use of the Leased Property to a third party, and in particular to sublet it, with the Lessor’s prior written consent. The Lessor shall refuse its consent only for good cause. Good cause within the meaning of this provision shall be deemed to exist, in particular, if the provisions of § 3 of this Agreement are violated or if the third party is in a competitive relationship with the Lessor with its services. The Lessor now agrees to subletting to affiliated companies pursuant to § 15 of the German Stock Corporation Act (AktG).

(2) In the event of the transfer of use to a third party, the Lessee shall be liable for the latter as its vicarious agent.
(1) The **Parties** agree that the above provisions are only practicable if they take consideration of the respective interests of the other **Party**, with the involvement of the other companies on site, and agree in particular to find mutually agreeable solutions to problems which cannot be foreseen and regulated in detail by a contract.

(2) This shall apply, in particular, to measures which the Parties carry out on their own responsibility and at their own expense in accordance with the provisions of this Agreement and to official and other requirements which can only be met by way of mutual agreement.

(3) In case of imminent danger, the **Lessee** shall comply with the instructions of the plant security provider and the plant fire department. It shall also impose this obligation on the personnel employed by it and on third parties commissioned by it.

(4) The placement and storage of objects of any kind (boxes, goods, etc.) outside the **Leased Property**, in particular in shared circulation routes, is not permitted. If, in exceptional cases, the **Lessor** grants its consent to such storage, the **Lessee** shall nevertheless be liable for any damage resulting therefrom.

(5) Packaging material or similar waste resulting from commercial activities may not be disposed of in the general household waste containers, but must be disposed of in the supply facilities designated for this purpose by the **Lessor**.

(6) The **Lessee** shall comply with the parking regulations (**Appendix 6**), ensure that its employees and visitors comply with the parking regulations and support the **Lessor** in enforcing the parking regulations to the best of its ability.
(1) This Agreement contains all agreements of the Parties. No additional agreements, ancillary agreements and assurances exist. If, contrary to the preceding sentence, additional agreements, ancillary agreements or assurances do exist, they are hereby revoked.

(2) Amendments and supplements to this Agreement and its Appendices as well as all declarations of intent under this Agreement must be made in writing to be effective. This shall also apply in the event of an amendment to this written form clause.

(3) The Parties are aware of the statutory written form requirement for lease agreements with a term longer than one year (§§ 550 (1), 126 (1) and (2) in conjunction with § 578 (2) (1) (1) BGB). They therefore mutually agree, upon mutual request of the other Party, to perform all acts and make all declarations necessary to comply with the statutory written form requirement. This provision shall apply not only to the execution of the main Lease Agreement and its Appendices, but also to all ancillary agreements, addenda, amendments or supplements. It shall not bind a subsequent purchaser of the property on which the Leased Property is located; § 566 (1) BGB shall be excluded to this extent.

(4) The Agreement shall be executed in duplicate; each Party shall receive one copy.

§ 22

Other provisions

(1) The Lessor, its agents, experts and interested parties may enter the Leased Property during business hours, after due notice and taking into account the legitimate interests of the Lessee, for the purpose of inspecting its condition, leasing it to a subsequent tenant, sale or otherwise for good cause.

Insofar as regulatory requirements (such as GMP regulations) apply to parts of the Leased Property, entry shall only be permitted in compliance with such requirements, insofar as the Lessee has provided timely and comprehensive information about the specific requirements and the necessary measures.
In case of imminent danger, they shall be permitted access at any time of the day or night. In this case, the Lessee shall provide the appropriate means of access and, if the Lessee is not present, shall deposit keys in a quickly accessible location known to the Lessor.

In addition, the Lessor and its agents shall be entitled to enter the Leased Property at any time of day or night in coordination with the Lessee (coordination documented, for example, by issuing an access authorization card) in order to access energy rooms, communication nodes, main and floor telephone exchanges, main and floor fire alarm exchanges, battery system rooms and electro-acoustic systems (ELA) including the infrastructure required for this purpose as well as other rooms serving the supply of the Leased Property.

(2) The Lessee shall be responsible for ensuring traffic safety within the Leased Property. The Lessee shall be responsible for ensuring safety within the leased areas used exclusively by it as well as the technical areas, insofar as these are also used exclusively by the Lessor.

Insofar as technical areas are used by both the Lessee and the Lessor (§ 1 (1) of the Lease Agreement), both Parties shall be equally liable for traffic safety and shall be jointly and severally liable to third parties in the event of a breach of the traffic safety obligation.

(3) All Appendices form an integral part of this Lease Agreement.

(4) As of the date of its entry into force, this Lease Agreement shall replace all existing oral and/or written agreements between the Parties concerning the transfer of the Leased Property described in more detail in § 1 of this Lease Agreement. The Old Lease existing between the Parties dated July 1, 2021 shall have ended as agreed with effect from the end of November 30, 2021, 12:00 a.m. the following day. No return of the Leased Property to the Lessee, even for a limited period of time, has taken place, as the Lessee continues to use the Leased Property without interruption.
This Agreement is independent of any other lease agreements existing between the Parties.

The Wastewater Agreement between the Lessor and the Lessee dated March 25/April 12, 2021 is an integral part of this Lease Agreement and is attached to this Agreement as Appendix 8.

The law of the Federal Republic of Germany shall apply to this Agreement and the lease governed by it. Insofar as translations are made of this Agreement, the German version shall be controlling.

Marburg/Lahn is agreed as the place of jurisdiction for all disputes arising from this Agreement.

Should any provision of this Agreement or any future newly included provision be invalid or unenforceable in whole or in part or lose its validity or enforceability at a later date, or should a gap be found in this Agreement, this shall not affect the validity of the remaining provisions. In place of the invalid or unenforceable provisions or to fill the gap, an appropriate provision shall be agreed in due form which, to the extent legally permissible, shall come as close as possible to what the Parties intended or would have intended according to the meaning and purpose of the Agreement if they had considered the point in question.

Marburg/Lahn is agreed as the place of jurisdiction for all disputes arising from this Agreement.

(10) The Lessor assumes no liability for any complete or partial competitive overlaps between the business operations of the Lessee and those of other tenants which exist or which will arise in the future. No protection against competition is granted.

The Appendices to this Agreement are:

Appendix 1) List of leased areas
Appendix 2.1) List of fixtures, installations and equipment, facilities
Appendix 2.2) Building description of the Leased Property, equipment description of the Leased Property
### Appendix 3
Lessee’s share of total area of Building M536 and Building M537 in m²

### Appendix 4
Monthly net base rent

### Appendix 5.1
Operating costs

### Appendix 5.2
Advance payment of operating costs

### Appendix 6
General Entry and Parking Regulations

### Appendix 7
Sample lease guarantee

### Appendix 8
Wastewater Agreement dated March 25/April 12, 2021 including Addendum No.1 dated December 14, 2021

### Appendix 9
Refurbishment of wastewater pipes

---

<table>
<thead>
<tr>
<th>Pharmaserv GmbH</th>
<th>BioNTech Manufacturing Marburg GmbH</th>
</tr>
</thead>
<tbody>
<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>[signature]</td>
<td>[signature]</td>
</tr>
</tbody>
</table>

---

<table>
<thead>
<tr>
<th>Name</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
</tbody>
</table>

---

<table>
<thead>
<tr>
<th>Name</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>[signature]</td>
<td>[signature]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
</tbody>
</table>
AMENDED AND RESTATED LICENSE AND COLLABORATION AGREEMENT

by and between

BioNTech SE

and

Genmab A/S

Effective as of 19 May 2015
TABLE OF CONTENTS

1. DEFINITIONS 5
2. PHASE A – RESEARCH AND EVALUATION 23
3. PHASE B – PRECLINICAL AND CLINICAL DEVELOPMENT 26
4. DEVELOPMENT OF PROPRIETARY COMBINATION PRODUCTS 31
5. MANUFACTURING IN RELATION TO COMBINATION STUDIES 38
6. COMMERCIALIZATION 40
7. REGULATORY MATTERS 43
8. REGULATORY MATTERS RELATING TO PROPRIETARY COMBINATION PRODUCTS 46
9. EXCLUSIVITY 48
10. FINANCIAL PROVISIONS 48
11. GOVERNANCE 58
12. INTELLECTUAL PROPERTY 65
13. INFRINGEMENT ACTIONS BROUGHT BY THIRD PARTIES 79
14. CONFIDENTIALITY 82
15. DATA PROTECTION 86
16. REPRESENTATIONS AND WARRANTIES 86
17. INDEMNITY AND LIMITATION OF LIABILITY 88
18. OPT-OUT 90
19. TERM AND TERMINATION 96
20. GENERAL PROVISIONS 98
LIST OF EXHIBITS

Exhibit 1  Terms for Unilateral Development
Exhibit 2  Biontech Patents
Exhibit 3  Genmab Patents
Exhibit 4  Antibody Panel
Exhibit 5  Company Announcement and Media Release
Exhibit 6  [***]
Exhibit 7  New Patents
Exhibit 8  Side Letter 5
Exhibit 9  Travel Policy
Exhibit 10  Permitted Subcontractors
Exhibit 11  Guiding Principles for [***] included in a Combination Products
Exhibit 12  Principles regarding Proprietary Combination Licenses
This Amended and Restated License and Collaboration Agreement (Agreement) is made and entered into as of 18th July 2022 (Execution Date) and with effect as of 19 May 2015 (Effective Date) by and between:

BioNTech SE, a German corporation having its principal office at An der Goldgrube 12, 55131 Mainz, Germany (Biontech), and

Genmab A/S, CVR no. 21023884, a Danish corporation located at Kalvebod Brygge 43, DK-1560 Copenhagen V, Denmark (Genmab).

(Biontech and Genmab each a Party and together the Parties)

PREAMBLE

WHEREAS, the Parties desire to jointly research, develop and commercialize polypeptide-based bispecific antibodies using Genmab’s proprietary DuoBody® platform technology against certain target combinations in combination with Genmab’s proprietary [***] technology for the treatment of cancer.

WHEREAS, the Parties have previously entered into a Letter of Intent (LOI) dated 19 January 2015 and a Materials Transfer Agreement dated 19 January 2015 (the MTA) (the LOI and the MTA together referred to as the Prior Agreement).

WHEREAS, the joint research, development and commercialization shall be based on a 50/50 sharing of costs and profits, whereby either Party shall have the right to exit its participation in further development costs at certain pre-defined opt-out points during development.

WHEREAS, based on the Prior Agreement, the Parties negotiated and entered into a license and collaboration agreement dated 19 May 2015 which was subsequently amended by amendment no. 1 dated 18 May 2017, amendment no. 2 dated 4 August 2017, amendment no. 3 dated 18 May 2018, amendment no. 4 dated 25 November 2019, amendment no. 5 dated 8 May 2020, amendment no. 6 dated 1 June 2021, amendment no. 7 dated May 12, 2022 and amendment no. 8 dated 24 May 2022 (together the Prior Collaboration Agreement). Additionally, the Parties entered into a first side letter dated 8 January 2016, side letter no. 2 dated 13 May 2016 (as amended by the amendment no. 1 to side letter no. 2 dated 19 May 2017, amendment no. 2 to side letter no. 2 dated 18 May 2018 as well as amendment no. 3 to side letter no. 2 dated 18 August 2020), side letter no. 3 dated 25 September 2017, side letter no. 4 dated 6 October 2020, side letter no. 5 dated 12 August 2021 (as amended by amendment no. 1 to side letter no. 5 dated 23 September 2021), side letter no. 6 dated 30 June 2022, a letter agreement dated 4 February 2020 (as amended by amendment of letter agreement dated 29 June 2020), a letter agreement dated 11 November 2020 with an effective date of 10 September 2020
as amended by amendment of letter agreement dated 15 December 2021, amendment no. 2 to letter agreement dated 30 May 2022 and amendment no. 3 to letter agreement dated 30 June 2022, and a letter agreement dated 4 June 2021 which are all related to but independent from the Prior Collaboration Agreement (the Side Letters).

WHEREAS, at the time of execution of the Prior Collaboration Agreement (and the first three (3) amendments thereto), BioNTech was still organized as a German “AG” (Aktiengesellschaft) and subsequently underwent a corporate form transition from the German “AG” to a European company (Societas Europaea or “SE”) which was published on 8 March 2019.

WHEREAS, the Parties wish to restate the Prior Collaboration Agreement in order to implement one coherent agreement incorporating all those amendments and additional terms agreed under the Side Letters since the Prior Collaboration Agreement came into effect to the extent they remain relevant from the Execution Date. The Parties agree that the terms of certain Side Letters are no longer relevant to the Parties’ continued performance of this Agreement after the Execution Date and, therefore, such terms have not been incorporated into this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the Parties hereby agree as follows:

1. DEFINITIONS

1.1 Adverse Event means any unfavorable and unintended medical occurrence in a human patient or subject who is administered a biopharmaceutical product or a combination of biopharmaceutical products, including without limitation any undesirable sign (including without limitation abnormal laboratory findings of clinical concern), symptom or disease temporally associated with the use of such biopharmaceutical product or combination, whether or not considered related to such biopharmaceutical product or combination.

1.2 Affiliate shall mean, with respect to any person or entity, any other person or entity which directly or indirectly controls, is controlled by, or is under common control with such person or entity. A person or entity shall be regarded as in control of another person or entity if it owns, or directly or indirectly controls, more than fifty percent (50%) of the voting stock or other ownership interest of the other person or entity, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other person or entity by any means whatsoever.

1.3 Agreed TSA has the meaning set forth in Section 3.11.

1.4 Alliance Manager has the meaning set forth in Section 11.1.

1.5 Antibody means a polypeptide-based antibody or a derivative thereof identifiable by a unique amino acid sequence [***]
1.6 **Applicable Law** means any law or statute (including without limitation anti-bribery or anti-corruption laws), any rule or regulation issued by a government authority (including without limitation courts and Regulatory Authorities), any GxP regulations or guidelines, any industry guidance to which a Party is subject, as well as any judicial, governmental, or administrative order, judgment, decree or ruling, in each case as applicable to the subject matter and the parties at issue.

1.7 **Applicable Taxes** has the meaning set forth in Section 10.17(b).

1.8 **Approved Subcontractor** means a subcontractor engaged by a Party as permitted in accordance with Sections 2.4(a), 2.4(b), or 3.3(a) and 3.3(b) of this Agreement (as applicable) to perform specific obligations of the subcontracting Party.

1.9 **Assigned Patents** shall have the meaning set forth in Section 12.1(g).

1.10 **Back-up Candidate** shall mean a Clinical Candidate that has been selected by the Joint Steering Committee as back-up candidate for a LCA Product or by the Continuing Party as a back-up candidate for a Unilateral Product in accordance with Section 2.12.

1.11 **Bidding Criteria** has the meaning set forth in Section 18.9(c).

1.12 **Biontech** has the meaning set forth in the introduction to this Agreement.

1.13 **Biontech Antibodies** mean the Antibodies proprietary to Biontech listed in the Research Plan.

1.14 **Biontech Improvement Technology** is defined in Section 12.1(c).

1.15 **Biontech Know-How** means any and all technical information, processes, formulae, data, inventions, methods, chemical compounds, biological or physical materials, know-how and other trade secrets, in each case that are not in the public domain, that relate to or are useful to research, develop, use, manufacture or commercialize the Biontech Antibodies, to the extent not disclosed or claimed by a Biontech Patent. Biontech Know-How shall include without limitation all Biontech Improvement Technology and Biontech’s interest in any Collaboration IP and Assigned Patents (in each case to the extent not disclosed or claimed by a Biontech Patent).

1.16 **Biontech Patents** means:

   (a) any Patent Rights listed in Exhibit 2 to this Agreement to the extent that they claim Biontech Antibodies, which shall be amended from time to time to reflect any other Patent Rights;

   (b) any Patent Rights covering Biontech Improvement Technology; and

   (c) Biontech’s interest in any Joint Patents and in any Patent Rights claiming Assigned Patents.

1.17 **Biontech Technology** means the Biontech Patents and the Biontech Know-How.

1.18 **Biontech Unilateral Product** means a Unilateral Product which is being developed and commercialized solely by Biontech.
1.19 **Bispecific Antibody** means an Antibody comprising antigen-binding sites of two different monoclonal Antibodies. The term Bispecific Antibody further includes without limitation the subtypes of [***] Antibodies having additional binding affinities to antigens or cells expressing such antigens.

1.20 **BLA** means a Biologics License Application or equivalent submission filed with the FDA and/or EMA in connection with seeking Marketing Approval of a biopharmaceutical product or a combination of biopharmaceutical products, or an equivalent application filed with any equivalent regulatory agency or governmental authority in any jurisdiction other than the United States.

1.21 **Business Day** means a day, other than a Saturday, Sunday, public holiday and/or bank holiday in Germany and/or Denmark.

1.22 **Calendar Quarter** means any of the three month periods beginning on January 1, April 1, July 1 or October 1 of any year.

1.23 **Ceased Product** has the meaning set forth in Section 18.4.

1.24 **Claims** has the meaning set forth in Section 17.1(a).

1.25 **Budget** shall mean the budget attached to the Research Plan or Development Plan or Commercialization Plan, as applicable.

1.26 **Clinical Candidate** means any Bispecific Antibody targeting any of the Target Combinations.

1.27 **Collaboration Accounting Policies** means the accounting policies as agreed to by the Parties and approved by the Joint Steering Committee to be used in determining Shared Costs, Shared Profits and Net Sales, which will be, in all material respects, consistent with IFRS and any Applicable Laws.

1.28 **Collaboration IP** has the meaning set forth in Section 12.1(c).

1.29 **Collaboration Product** means any LCA Product or [***].

1.30 [***] has the meaning set forth in Section [***].

1.31 **Collaboration Targets** means the following antigens: [***] (also known as [***]), [***] (also known as [***]), [***], [***] and [***]. Further Collaboration Targets may be added through written amendment of the Research Plan.

1.32 **Commercialization** means (i) all activities directed to the marketing, detailing, promotion (including co-promotion), advertising, selling and distribution of a LCA Product in a country or region after all Marketing Approvals have been obtained in such country or region (including without limitation making, having made, using, importing, selling, having sold, offering for sale, and having offered for sale such LCA Product), and will include without limitation marketing research, customer service, administering and commercially selling such LCA Product, post-approval clinical trials and other additional research and development activities.
undertaken solely and to the extent necessary to meet local regulatory requirements, importing, exporting or transporting such LCA Product for commercial sale, and all regulatory compliance with respect to the foregoing; it being understood and agreed that such activities may occur pre- or post-launch of such LCA Product; and (ii) the conclusion of one or more Partnership Agreements. When used as a verb, “Commercialize” means to engage in Commercialization.

1.33 **Commercialization Agreement** has the meaning set forth in Section 6.5.

1.34 **Commercialization Plan** means, with respect to a LCA Product, a commercialization plan to be prepared and agreed between the Parties, and updated by the Joint Commercialization Committee, once such committee is in place, and endorsed by the Joint Steering Committee which describes the envisaged form of Commercialization (e.g. through own sales forces, third party sales forces, conclusion of Partnership Agreements, etc.), the responsibilities of each Party, timelines, budgets for Commercialization costs, target volumes, territories and other relevant items agreed between the Parties. The Commercialization Plan shall be carried out by the Joint Commercialization Committee and shall be updated at least annually by the Joint Commercialization Committee, once such committee is in place, and all changes to the Commercialization Plan must be approved by the Joint Steering Committee.

1.35 **Commercially Reasonable Efforts** means the level of efforts and resources that a similarly situated company in the biotechnology industry would normally use to accomplish a similar objective, and in particular with respect to a product: to develop, manufacture and commercialize a product of similar market potential at a similar stage in its development or product life cycle taking into account all relevant factors then prevailing, including without limitation efficacy, competition, intellectual property position, likelihood of Marketing Approval, profitability, alternative products and product candidates and other relevant factors.

1.36 **Confidential Information** means all information, data, documents including know-how and the subject-matter of any unpublished invention, or any material in tangible form that is disclosed or made available under this Agreement by the Disclosing Party to the Receiving Party and that is marked as “Confidential” at the time it is disclosed or delivered to the Receiving Party (or, if disclosed orally, is identified as confidential when disclosed and such disclosure is confirmed in writing within thirty (30) days by the Disclosing Party) or ought in good faith to be treated as confidential taking account of its content or the circumstances of disclosure. The term Confidential Information shall also include the existence and contents of this Agreement.

1.37 **Continuing Party** has the meaning set forth in Section 18.5.

1.38 **Continuing Side Letters** means: (i) the letter agreement dated 11 November 2020 with an effective date of 10 September 2020 (as amended by amendment of letter agreement dated 15 December 2021 and amendment no. 2 to letter agreement dated 30 May 2022) entered into by the Parties; and (ii) side letter no. 6 dated 30 June 2022 entered into by the Parties.
1.39 Data Protection Agreement has the meaning set forth in Section 15.

1.40 Developing Party means, in relation to [***], the Party that, as between the Parties, possesses the right to [***], [***] and/or [***] (or [***] [***]) included in such [***] and wishes to research and/or develop such [***] under this Agreement.

1.41 Development means, with respect to an LCA Product, any and all drug development activities and manufacturing activities undertaken pursuant to the relevant Development Plan in order to develop an LCA Product up to and including obtaining Marketing Approval for such LCA Product for an indication and to perform manufacturing scale up to enable commercial scale manufacturing prior to launch (except that inventory build shall be considered a Commercialization activity). These activities shall include without limitation preclinical and translational research, stability testing, toxicology testing, formulation activities, reformulation activities, process development, manufacturing scale up activities, development stage manufacturing, quality assurance/quality control development, clinical studies (including without limitation Phase III Studies and other studies (e.g., pharmacovigilance programs and outcome studies) that the Joint Steering Committee considers necessary or economically justifiable and other activities to obtain the applicable Marketing Approvals; in each case in accordance with the applicable Development Plan, as applicable. When used as a verb, Develop means to engage in Development.

1.42 Development Plan means, with respect to an LCA Product, a written development plan approved by the Joint Steering Committee which describes the Development and manufacturing work to be performed by each Party during Phase B, as well as the Budgets, approved Shared Costs, timelines, allocation of FTEs and other relevant items agreed between the Parties.

1.43 Development Team Leader has the meaning set forth in Section 11.5(e).

1.44 Disclosing Party has the meaning set forth in Section 14.1.

1.45 Divestment shall mean the economic valorization of the value of the rights and obligations of the Parties under this Agreement, by granting the rights to Develop and/or Commercialize an LCA Product to an independent Third Party in any legal way possible, including but not limited to by licensing, assigning or transferring such rights. When used as a verb, Divest means to engage in Divestment.

1.46 Divestment Executive has the meaning set forth in Section 18.9(b).

1.47 Dual- or Triple-Binder [***].

1.48 DuoBody Platform means Genmab’s proprietary technology that is generally applicable to the discovery, modification, optimization, generation and manufacturing of Bispecific Antibodies of the IgG subtype [***].
1.49 **Effective Date** has the meaning set forth in the introductory paragraph of this Agreement.

1.50 **EMA** means the European Medicines Agency, and any successor agency thereto.

1.51 [[[***]]] **Tumor Targeting Product Concept** means any one of the product concepts listed below:
- [[[***]]]
- [[[***]]]
- [[[***]]]

1.52 **Establishment of Clinical Proof of Concept** means the point in time during Development, where the [[[***]]] from the first Phase I/II Clinical Trial becomes available.

1.53 **EU** means all the countries in the Territory that as of the receipt of the European Marketing Approval for an LCA Product are members of the European Union.

1.54 **Events of Force Majeure** has the meaning set forth in Section 19.7.

1.55 **Execution Date** has the meaning set forth in the introductory paragraph of this Agreement.

1.56 **FDA** means the U.S. Food and Drug Administration, or any successor agency thereto.

1.57 **Field** means the treatment of cancer in humans.

1.58 **Financial Representative** has the meaning set forth in Section 10.10.

1.59 **First Commercial Sale** means, on a Unilateral Product-by-Unilateral Product basis, the first sale of the Unilateral Product for which revenue has been recognized by a Party or any of its Affiliates to any Third Party after all required Marketing Approvals have been granted. For the avoidance of doubt, First Commercial Sale shall not include the transfer or sale of any Unilateral Product (i) by a Party to an Affiliate, Sublicensee or Third Party Collaborator unless the Affiliate, Sublicensee or Third Party Collaborator is the last entity in the distribution chain of the Unilateral Product; (ii) for use in clinical trials or non-clinical development activities (e.g., material transfer agreements) or a bona fide charitable purpose, or (iii) for compassionate use.

1.60 **FTE** means a full-time employee of a Party working over the course of a twelve (12) month period, or several employees of a Party collectively working the equivalent of such full-time employee. FTEs shall be calculated based on the time an employee of the Parties spends working on a billable effort as recorded by such Parties’ project time reporting system. An FTE is measured on the basis of a total of [[[***]]] hours per year for employees.

1.61 **FTE Fee** shall mean the fee set forth in Exhibit 1.

1.62 **FTE Rate** shall mean the rate set forth in Sections 10.7.
1.63 **FTO Notification** has the meaning set forth in Section 13.1 of this Agreement.

1.64 **Generic Product** means:

(a) for a product sold in the United States, a biological product approved under the Public Health Service Act 351(k) that is highly similar to a Unilateral Product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the generic product and the Unilateral Product in terms of the safety, purity and potency;

(b) for a product sold in the EU, a biological product approved under Article 10(4) of Directive 2001/83/EC and Section 4, Part II, Annex I to such Directive based on the demonstration of the similar nature to the Unilateral Product; and

(c) for a generic product sold outside the United States and the EU, a biological product approved under a similar regulatory pathway as in the United States and in the EU, if such pathway exists.

1.65 **Genmab** has the meaning set forth in the introduction to this Agreement.

1.66 **Genmab Antibodies** means the [***] Antibodies and [***] Antibodies as well as further Antibodies proprietary to Genmab that may be included in the collaboration of the Parties under this Agreement and listed in the Research Plan upon prior written mutual agreement.

1.67 **Genmab Improvement Technology** has the meaning set forth in Section 12.1(c).

1.68 **Genmab Know-How** means all technical information, processes, formulae, data, inventions, methods, chemical compounds, biological or physical materials, know-how and other trade secrets, in each case, that relate to or are useful to research, develop, manufacture or commercialize the Genmab Antibodies, the DuoBody Platform and/or the [***] Technology, to the extent not disclosed or claimed by a Genmab Patent. Genmab Know-How shall include without limitation all Genmab Improvement Technology and Genmab’s interest in any Collaboration IP and Assigned Patents (in each case to the extent not disclosed or claimed by a Genmab Patent).

1.69 **Genmab Patents** means:

(a) any Patent Rights listed in Exhibit 3 to this Agreement to the extent that they claim Genmab Antibodies, the DuoBody Platform or the [***] Technology, which shall be amended from time to time to reflect any other Patent Rights;

(b) any Patent Rights covering Genmab Improvement Technology; and

(c) Genmab’s interest in any Joint Patents and in any Patent Rights claiming Assigned Patents.
1.70 Genmab Technology means the Genmab Patents and the Genmab Know-How.

1.71 Genmab Unilateral Product means a Unilateral Product which is being developed and commercialized solely by Genmab.

1.72 Good Clinical Practice or GCP shall mean 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(R1), current step 4 version, dated 10 June 1996, as amended from time to time, national legislation implementing European Community Directive 2001/20/EC of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, European Community Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards to investigational medicinal products for human use.

1.73 Good Laboratory Practice or GLP shall mean 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 Directive 2004/9/EC of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) as amended and European Community Directive 2004/10/EC of 11 February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances as amended, OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring.

1.74 Good Manufacturing Practice or GMP shall mean 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, Commission Directive 2003/94/EC as amended from time to time, EudraLex – Volume 4 of the Rules Governing Medicinal Products in the European Union including annexes, the EU Clinical Trial Regulation 536/2014, Commission Delegated Regulation 2017/1569 and Detailed Commission Guideline (2017) 8179.

1.75 GxP means GCP, GLP or GMP or any combination thereof, as applicable.

1.76 IFRS means the international financial reporting standards.

1.77 Improvement Technology means either Genmab Improvement Technology or Biontech Improvement Technology, as applicable.
1.78  IND means an Investigational New Drug application filed with the FDA, EMA or their equivalent in any country where a regulatory filing is required or obtained for commencement of human clinical trials of a pharmaceutical product.

1.79  Indication means an application for a label or label expansion indicating the applicable drug for an initial, expanded or additional patient population, or indicating the drug for use in combination with another treatment or drug, or different route of administration in each case that requires a Phase III Clinical Trial for Marketing Approval. For the avoidance of doubt, the Parties acknowledge that there may be more than one Indication for any given histology or tumor type. By way of example, and not limitation, mono-therapy, various combination therapies, front-line treatment and maintenance treatment of the same histology or tumor type are different Indications for the purposes of this Agreement.

1.80  Indemnified Party has the meaning set forth in Section 17.4.

1.81  Indemnities has the meaning set forth in Section 17.1(a).

1.82  Indemnitor has the meaning set forth in Section 17.4.

1.83  [***] Technology means Genmab’s proprietary [***] technology to control the immune response induced by antibodies [***].

1.84  Infringement Attack has the meaning set forth in Section 13.2.

1.85  Infringement Proceedings has the meaning set forth in Section 12.12(d).

1.86  IP Budget has the meaning set forth in Section 12.8(d).

1.87  Joint Combination Product means: (i) a pharmaceutical product suitable for human therapeutic application in the Field which consists of [***] and [***] or [***] (and potentially [***]), which may be sold separately but are allowed to be administered together under the relevant Marketing Approvals; or [***] a [***]. For clarity, a Joint Combination Product shall not include [***].

1.88  Joint Commercialization Committee means the joint commercialization committee established under Section 11.6.

1.89  Joint Development Team has the meaning set forth in Section 11.5.

1.90  Joint Divestment Process has the meaning set forth in Section 18.9.

1.91  Joint Patents means any patents and patent applications claiming Collaboration IP, including without limitation the New Patents to the extent provided for in Exhibit 7.

1.92  Joint Research Committee means the joint research committee established under Section 11.2.

1.93  Joint Steering Committee means the joint steering committee established under Section 11.3.
1.94 **LCA Product** means a Clinical Candidate which the Parties have selected for further joint development in Phase B.

1.95 **LCA Product Trademark** has the meaning set forth in Section 12.14.

1.96 **Lead Commercialization Party** has the meaning set forth in Section 6.3.

1.97 **Lead IP Party** has the meaning set forth in Section 12.8(a).

1.98 **Lead Regulatory Party** means, on an LCA Product-by-LCA Product basis, with respect to a country or region, the Party with the main responsibility for carrying out regulatory activities in accordance with Section 7.

1.99 **Liabilities** has the meaning set forth in Section 17.1(a).

1.100 **Major Market Country** means any of the following: [***].

1.101 **Marketing Approval** means any regulatory approval of any Regulatory Authority or other government authority of any country or jurisdiction in the world that is necessary to be obtained before the commercial sale of a pharmaceutical product for an Indication in that country or jurisdiction.

1.102 [***] has the meaning set forth in Section 1.103.

1.103 [***] **Agreement** means the Amended and Restated Evaluation and Commercialization Agreement, entered into as of July 12, 2012, but effective as of February 25, 1999 by and between [***] and Genmab A/S for using [***] for generating and developing antibodies for treatment of humans. A redacted copy of the [***] Agreement shall be provided to Biontech upon request.

1.104 **Meetings** has the meaning set forth in Section 11.7.

1.105 **Net Sales** means the gross amounts invoiced in arms-length transactions by a Party or any of its Affiliates, Third Party Collaborators or Sublicensees to Third Party customers for sales of an LCA Product or Unilateral Product (or in the case of [***], such sales of a Collaboration Product), in accordance with Collaboration Accounting Policies consistently applied, less the following deductions for:

(a) discounts (including without limitation trade, quantity and cash discounts) actually allowed, cash and non-cash coupons, retroactive price reductions, and charge-back payments and rebates granted to any Third Party (including without limitation to governmental entities or agencies, purchasers, reimbursers, customers, distributors, wholesalers, and group purchasing and managed care organizations or entities);

(b) credits or allowances, if any, on account of price adjustments, shelf stock adjustment, recalls, claims, damaged goods, rejections or returns of items previously sold (including without limitation products returned in connection with recalls or withdrawals) and amounts written off by reason of uncollectible debt, provided that if the debt is thereafter paid, the corresponding amount will be added to the Net Sales of the period during which it is paid;
product-related administrative fees, rebates or other similar allowances granted (including without limitation to governmental authorities, purchasers, reimbursers, customers, distributors, wholesalers, and managed care organizations and entities) which effectively reduce the selling price or gross sales; and

(d) insurance, customs charges, freight, postage, shipping, handling, and other transportation costs; and

(e) import taxes, export taxes, excise taxes, sales taxes, value-added taxes, consumption taxes, duties or other taxes levied on, absorbed, determined and/or imposed with respect to sales of LCA Products (excluding income taxes of any kind).

All of the foregoing deductions set forth in items (a)-(e) above from the gross amount invoiced for such sales of both LCA Products and Unilateral Products shall be determined in accordance with Collaboration Accounting Policies consistently applied.

If a Party receives non-cash consideration or in the case of transactions not at arm’s length, Net Sales will be calculated based on the fair market value of such consideration or transaction, at the time of the transaction, assuming an arm’s length transaction made in the ordinary course of business. Notwithstanding the foregoing, Net Sales shall not be imputed to any transfer of the LCA Product or Unilateral Product for use in clinical trials, non-clinical development activities (e.g. material transfer agreements) or other development activities with respect to the LCA Product or Unilateral Product by or on behalf of the respective Party, for bona fide charitable purposes or for compassionate use, if no monetary consideration is received for such transfers.

If any [***] is sold in a given country and reporting period for a single invoice price, “Net Sales” (for the purpose of determining (i) royalties and sales milestones applicable to [***] included in such [***] in such country or (ii) Profits applicable to any [***] included in such [***] in such country):

(a) will be calculated by multiplying actual Net Sales of such [***] by the fraction [***].

(b) if, on a country-by-country basis in a particular reporting period, the [***] or [***], as applicable, included in [***] is sold separately in the same Indication in a country, but the [***], [***], and [***] included in [***] are not sold separately in the same Indication in such country, then Net Sales will be calculated by multiplying actual Net Sales of such [***] by the fraction [***].

(c) if, on a country-by-country basis in a particular reporting period, the [***] or [***], as applicable, included in the [***] is not sold separately in the same Indication in such country, but the [***], [***] and [***] included in [***] are sold separately in the same Indication in such country, then Net Sales will be calculated by multiplying actual Net Sales of the [***] by the fraction [***].
(d) if none of the above is applicable in a given country during a particular reporting period, then Net Sales shall be determined by the Parties in good faith taking into account the above value allocation principles and based on the relative fair market value of the [***] or [***], as applicable, and each of the [***], [***], and [***] included in such [***] when sold in such Indication in such country and in accordance with Collaboration Accounting Policies consistently applied.

1.106 **New Patients** has the meaning set forth in Section 12.1(f).

1.107 **Non-Collaboration Product** means an [***] or [***] which, as between the Parties, is owned or controlled by the Party [***] such [***] and which is [***] and/or [***] (whether [***] or [***]) by or on behalf of such Party (alone or in collaboration with [***]) outside the scope of this Agreement, [***] or [***]. For clarity, subject to the terms of Exhibit 11 and Sections 3.13(c) and 3.13(d), the term [***] explicitly excludes any [***], [***], and any [***], but includes any [***] (as such term is defined in this Agreement or [***]).

1.108 [***] has the meaning set forth in Section [***].

1.109 **Non-Developing Party** means the Party other than the Developing Party.

1.110 **Non-Lead Party** has the meaning set forth in Section 12.8(b).

1.111 [***] has the meaning set forth in Section 1.112.

1.112 [***] Agreement means the [***] entered into by Genmab, Genmab B.V. and [***] ([***]), dated October 1, 2014 for the development and commercialization of products generated by Genmab and/or Genmab B.V. using the [***] Technology (as that term is defined in the [***] Agreement). A summary of the financial terms for the development and commercialization of products generated under this [***] Agreement is set forth in Exhibit 6. A redacted copy of the [***] Agreement has been provided to Biontech pursuant to side letter no. 4 dated 6 October 2020.

1.113 **Opt-Out Date** has the meaning set forth in Section 18.1.

1.114 **Opt-Out Notice** has the meaning set forth in Section 18.1.

1.115 **Opt-Out Party** has the meaning set forth in Section 18.1.

1.116 **Opt-Out Point** has the meaning set forth in Section 18.1.

1.117 **Out of Scope Divisional** has the meaning set forth in Section 8 of Exhibit 7.

1.118 **Out of Scope Matter** has the meaning set forth in Section 6 of Exhibit 7.
1.119 Partnership Agreement means a license agreement to be concluded jointly by both Parties (or by one of the Parties with approval of the other Party) with a Third Party (Third Party Collaborator) under which such Third Party Collaborator obtains an exclusive or non-exclusive (as agreed between the Parties and the Third Party Collaborator in accordance with Section 6.7) license or other right to an LCA Product and related Collaboration IP and assumes the obligation to Commercialize such LCA Product in certain defined parts of the Territory.

1.120 Patent Right means (a) all patent applications filed or having legal force in any country or jurisdiction, including without limitation all provisional patent applications; (b) all patents that have issued or in the future will be issued from such applications, including without limitation method, process, utility, model and design patents and certificates of invention; and (c) all divisions, continuations, continuations in part, supplement protection certificates, reissues, reexaminations, renewals, extensions or additions to any such patent application and patents.

1.121 Paying Party has the meaning set forth in Exhibit 1.

1.122 [***] Antibodies means the [***] Antibodies against [***] proprietary to Genmab, which have been generated by Genmab using the [***] technology pursuant to the [***] Agreement.

1.123 [***] Tumor Targeting Product Concept means any one of the product concepts listed below:

[***]

[***]

[***]

[***]

[***]

For the avoidance of doubt, the term [***] Tumor Targeting Product Concept shall also include abovementioned product concepts whose mode-of-action may rely, in whole or in part, on transactivation of T cells and antigen-presenting cells, or, as the case may be, on any other mode-of-action as may be revealed by future preclinical and/or clinical research.

1.124 [***]

1.125 [***]

1.126 Permitted Subcontractor means each entity listed in Exhibit 10 as updated from time to time in accordance with Sections 11.2(a)(v), 11.3(a)(xvi), 11.3(a)(xvii) or 20.5.

1.127 Phase I Clinical Trial means, a human clinical trial that is conducted to evaluate the preliminary safety, tolerability and pharmacokinetics effect of a drug in healthy volunteer subjects or patients in accordance with the requirements of 21 CFR 312.21(a) or foreign equivalents.
1.128 **Phase I/II Clinical Trial** means a human clinical trial which has the following two (2) main objectives: (i) determining preliminary safety and (ii) determining preliminary efficacy parameters in appropriate patients. Such Phase I/II Clinical Trial will often be split into two (2) parts, where the first part is intended to determine the maximum tolerated dose, and the second part is intended to determine preliminary efficacy parameters and additional safety data.

1.129 **Phase II Clinical Trial** means a potentially controlled human clinical trial involving a sufficient number of patients with the disease or condition of interest to obtain sufficient efficacy and safety data of a candidate drug in the targeted patient population to support a Phase III Clinical Trial of a candidate drug for its intended use, and to define the optimal dosing regimen, such as trials referred to in 21 C.F.R. §312.21(b) and foreign equivalents.

1.130 **Phase III Clinical Trial** means a controlled, and usually multi-center, clinical trial, involving patients with the disease or condition of interest intended to obtain sufficient efficacy and safety data to support Marketing Approval of a candidate drug whether or not designated as “Phase III”, such as trials referred to in 21 C.F.R. §312.21(c) and foreign equivalents. For clarity, a Phase II Clinical Trial intended to obtain sufficient efficacy and safety data to support Marketing Approval of a candidate drug shall qualify as a Phase III Clinical Trial.

1.131 **Phase A** means the research and evaluation phase pursuant to Section 2.

1.132 **Phase B** means the preclinical and clinical development phase pursuant to Section 3.

1.133 **PMA** means a U.S. premarket approval application for a Class III medical device filed with the FDA, or an equivalent application filed with any equivalent regulatory agency or governmental authority in any jurisdiction other than the United States.

1.134 **Preferred Clinical Candidate** has the meaning set forth in Section 2.10.

1.135 **Prior Agreement** has the meaning set forth in the preamble of this Agreement.

1.136 **Prior Collaboration Agreement** has the meaning set forth in the preamble of this Agreement.

1.137 **Profit** means the profits resulting from the Commercialization of an LCA Product, which shall be equal to the Net Sales received by a Party from the Commercialization of an LCA Product:

(a) less manufacturing costs for the LCA Product sold,
plus profits received from Partnership Agreements in relation to the LCA Product, provided, however, that any costs that would otherwise be included as a Commercialization expense, but which, pursuant to the definition of “Net Sales”, are deducted from gross sales to determine the Net Sales of an LCA Product, shall not also be deducted as a Commercialization expense and thereby counted twice. For the avoidance of doubt, Profits received from Partnership Agreements shall include without limitation all up-front, milestone and royalty payments, but exclude (i) any arms’ length research and development funding paid by the Third Party Collaborator in consideration for research and development activities to be performed under the Partnership Agreement and (ii) any value added or other taxes paid by the Third Party Collaborator to a Party in connection with such Partnership Agreement. Further details of the Profit calculation shall be agreed in the Commercialization Agreement.

1.138 Program Inventions has the meaning set forth in Section 12.1(b).

1.139 Proposed IND Submission has the meaning set forth in Section 3.8.

1.140 Proprietary Combination [***] Plan has the meaning as set forth in Section 4.3(c).

1.141 Proprietary Combination Product means a pharmaceutical product suitable for human therapeutic application in the Field which includes [***] (and, potentially, [***] or [***]) and [***] or [***], which may be sold separately but are allowed to be administered together under the relevant Marketing Approvals. A Proprietary Combination Product may also include [***] (save that [***] shall constitute a [***] in the circumstances described in Sections 3.13(c) and 3.13(d) and/or [***] or [***], in each case if approved by the Joint Steering Committee.

1.142 Proprietary Combination Product IP has the meaning set forth in Section 12.2(a).

1.143 Proprietary Combination Study means (a) a [***] study of a Proprietary Combination Product or (b) a [***] study using a [***] in combination with a [***] which (i) serves as substitute for the [***] selected for the relevant combination and (ii) is accepted by the competent Regulatory Authority to act as surrogate for the purposes of such [***] study.

1.144 Publication has the meaning set forth in Section 14.5.

1.145 Receiving Party has the meaning set forth in Section 14.1.

1.146 Region means either Asia (including, but not limited to India), the EU, North America (US, Mexico and Canada), South and Central America or ROW (including, but not limited to Russia, Australia, New Zealand, Africa, Middle East).

1.147 Regulatory Authority means any federal, national, multinational, state, county, city, provincial, or local regulatory agency, department, bureau or other governmental entity with authority over the marketing, commercialization, manufacture or sale of a pharmaceutical product in the Territory, including without limitation the FDA in the United States and the EMA in the EU.
1.148 Research and Development Costs means the actual costs and expenses incurred by a Party for research and Development activities in Phase A and Phase B, including without limitation:

(a) direct labor at the agreed FTE Rate plus agreed travel expenses pursuant to the Travel Policy of such employees,
(b) direct research and Development costs paid to consultants, independent contractors and Third Party service providers,
(c) direct costs of supplies, equipment and materials and related expenditures (including without limitation taxes and duties),
(d) patent filing, prosecution and maintenance costs (but not defense and enforcement costs, unless otherwise set forth in this Agreement),
(e) scale-up and other manufacturing costs (solely up to and including scale-up activities prior to production of successful consistency batches which is understood to be the first production of batches of an LCA Product that may be used for Commercialization),
(f) Third Party contract costs required to perform Development activities related to the relevant LCA Product,
(g) regulatory costs, including without limitation (1) costs for IND and BLA filing, (2) costs for PMA filing (if applicable) and (3) other costs for obtaining Marketing Approvals,
(h) license payments (including but not limited to upfront payments, milestone payments and license maintenance fees) to Third Parties as necessary for Development and Commercialization of LCA Products

in each case (a) to (h) calculated in accordance with the Collaboration Accounting Policies, consistently applied and only to the extent such costs are directly attributable to the furthearance of a Research Plan or Development Plan, but excluding expenditures relating to general overhead, managerial, legal, financial and administrative expenses. For the avoidance of doubt, to the extent costs or salaries are partly directly attributable to a Research Plan or Development Plan and partly attributable to other activities of a Party, such costs and salaries shall constitute Research and Development Costs on a pro rata basis.

1.149 Research Plan means the written research plan approved by the Joint Research Committee (including, for the avoidance of doubt, any reports (in the form of PowerPoint presentations) provided to and approved by the Joint Research Committee) which describes the work to be performed by each Party during Phase A as well as budgets, timelines, allocation of FTEs and other relevant items agreed between the Parties. The Research Plan shall be updated at least annually.
1.150 **Royalty Reports** has the meaning set forth in Exhibit 1.

1.151 **Royalty Term** means on a Unilateral Product-by-Unilateral Product and country-by-country basis, the period commencing on the First Commercial Sale of the relevant Unilateral Product and ending on the later to occur of:

(a) the [***] anniversary of the date of the First Commercial Sale of such Unilateral Product in such country;

(b) the expiration of the last to expire Valid Patent Claim of any Patent Right included in the [***] or the [***] (in case of an opt-out by Genmab) or [***] (in case of an opt-out by Biontech) that would be infringed by the manufacture, use, sale, offer for sale or import of the Unilateral Product in such country by a Third Party without a license; and

(c) the expiration of [***] for such Unilateral Product in such country.

1.152 **Selection of a Clinical Candidate** has the meaning set forth in Section 2.10.

1.153 **Serious Adverse Events** means any Adverse Event occurring at any dose in response to the administration of a biopharmaceutical product or a combination of biopharmaceutical products that: (a) results in death or threatens life; (b) results in persistent or significant disability/incapacity; (c) results in or prolongs hospitalization; (d) results in a congenital anomaly or birth defect; or (e) is otherwise medically significant.

1.154 **Shared Costs** has the meaning set forth in Section 10.8(a).

1.155 **Shared Costs Report** has the meaning set forth in Section 10.11.

1.156 **Shared Profits** has the meaning set forth in Section 10.8(b).

1.157 **Side Letters** has the meaning set forth in the preamble of this Agreement.

1.158 **Standalone Agreement** means any agreement which may be entered into from time to time between Biontech and Genmab (or any of their Affiliates) relating to the research, development and/or commercialization of [***], including without limitation [***], [***].

1.159 **Standalone Product** means any product that is researched, developed and/or commercialized pursuant to a Standalone Agreement.

1.160 **Sublicensee** means any person or entity that is granted a sublicense under (a) the Biontech Technology by Genmab or its Affiliates or (b) the Genmab Technology by Biontech or its Affiliates, in each case (a) and (b) in accordance with the terms of this Agreement.

1.161 **Target Combination** means each of the combinations of two distinct targeted antigens selected from the Collaboration Targets as specifically set forth in the Research Plan; each distinct antigen defined by its unique UniProt/Swiss-Prot number.

1.162 **Technology** means either Biontech Technology or Genmab Technology, as applicable.
1.163 **Term** has the meaning set forth in Section 19.1.
1.164 **Territory** means the world.
1.165 **Third Party** means any person or entity other than the Parties and their Affiliates.
1.166 **Third Party Combination Product** means a pharmaceutical product suitable for human therapeutic application in the Field which consists only of: [[[*]] or [[***]] (and, potentially, [[*]] or [[**]] and/or the [[***]] and [[*]] irrespective of [[**]]) in each case which may be sold separately but are allowed to be administered together under the relevant Marketing Approvals, and which the Parties agree to develop and commercialize jointly under this Agreement. For clarity, a Third Party Combination Product shall not include [[***]].
1.167 **Third Party Product** means an [[***]] or [[***]] owned or controlled by a Third Party. For the avoidance of doubt, [[***]] shall not be regarded as “Third Party Product” under this Agreement, but shall constitute [[***]].
1.168 [[***]] has the meaning set forth in Section 3.11.
1.169 [[***]] MSA has the meaning set forth in Section 3.11.
1.170 **Travel Policy** means the policy as agreed to by the Parties and approved by the Joint Steering Committee to be used for travel costs and expenses incurred as part of a Party’s activities under the applicable Research Plan or Development Plan, subject however to Sections 10.10 and 11.7. The Travel Policy that is in effect as of the Execution Date is attached hereto as Exhibit 9.
1.171 **TSA** has the meaning set forth in Section 3.11.
1.172 **Unilateral Product** has the meaning set forth in Section 18.5.
1.173 **Valid Patent Claim** means (a) an unexpired claim of an issued patent (including without limitation any extension thereof pursuant to patent term extension or a supplementary protection certificate) which has not been found to be unpatentable, invalid or unenforceable by an unreversed and unappealable decision (including without limitation a decision that was not appealed within the time allotted for an appeal) of a court or other authority in the subject country; or (b) a claim of an application for a patent that has been pending for less than [[***]] years as calculated from the earliest priority date.
1.174 **[***] Antibodies** means the [[***]] Antibodies against [[***]] proprietary to Genmab, which have been generated by Genmab using [[***]] transgenic mouse technology pursuant to the [[***]] Agreement.
1.175 **Within Scope Matter** has the meaning set forth in Section 2 of Exhibit 7.
2. PHASE A – RESEARCH AND EVALUATION

2.1 Goal of Phase A. The goal of Phase A is to jointly discover, research and develop in accordance with the Research Plan, Clinical Candidates against the Target Combinations for further preclinical and clinical development in Phase B, on the basis of a 50/50 cost sharing. During the initial term of Phase A (as specified in Section 2.5), the Parties expect to identify [* ***] Clinical Candidates. For the avoidance of doubt, these numbers of expected Clinical Candidates are non-binding estimates only and the collaboration between the Parties in Phase A shall not be subject to any binding minimum or maximum number of Clinical Candidates. The Parties agree that this Agreement shall replace the Prior Agreement on the Effective Date, and that any initial research (as defined under the Prior Agreement) conducted under the Prior Agreement shall be deemed covered by Phase A and the terms and conditions thereof, and any rights and obligations of the Parties under the Prior Agreement shall be replaced with the rights and obligations of the Parties set forth in this Agreement. In case of discrepancy between this Agreement and the Prior Agreement, this Agreement shall prevail.

2.2 Research Plan. Within [* ***] after the Effective Date, the Parties shall prepare and agree an initial Research Plan, which shall be endorsed by the Joint Research Committee. On an annual basis, or more frequently as necessary and agreed by the Parties, but no later than by 30 September (in order for the Parties to prepare their respective budgets for the coming [* ***] calendar years) the Joint Research Committee shall review the Research Plan in order to make annual updates to the Research Plan for the then current calendar year, if any, plus the following two (2) calendar years. Furthermore, each Party may recommend changes to the Research Plan at any time; provided, however, that such changes shall be effective only upon the approval by the Joint Research Committee.

2.3 FTE Allocation During Phase A. The Parties intend to contribute and commit the required resources to meet the objectives as stipulated by the Joint Research Committee and in the applicable Research Plan. Details in relation to the number and allocation of FTEs during Phase A shall be set forth in the Research Plan. For the avoidance of doubt, the allocation of FTEs pursuant to the Research Plan shall not alter the 50/50 cost sharing in Phase A as set forth in Section 10.8(a).

2.4 Subcontracting During Phase A.

(a) Subject to Sections 2.4(b) and 2.4(c), each Party may perform some or all of its obligations under or relating to the Research Plan through any of its Affiliates or one or more Third Parties.

(b) Notwithstanding Section 2.4(a), and subject to Section 2.4(c), neither Party may subcontract any of its obligations under the Research Plan relating to non-clinical experiments or studies, or the formulation, process development, and manufacture of a Clinical Candidate or a component thereof, without the prior approval of the Joint Research Committee, unless such subcontractor is an Affiliate or Permitted Subcontractor (in which case no such Joint Research Committee approval shall be required).
(c) The subcontracting Party shall ensure that: (i) any such Approved Subcontractor shall perform such subcontracted obligations pursuant to a written agreement; (ii) none of the rights of the other Party hereunder are diminished or are otherwise adversely affected as a result of such subcontracting; and (iii) the Approved Subcontractor undertakes in writing all obligations of confidentiality and non-use regarding both Parties’ Confidential Information which are substantially the same as those undertaken by the Parties hereunder. In the event that a Party performs one or more of its obligations under the Research Plan through any such Approved Subcontractor, then such Party shall at all times be responsible for the performance by such Approved Subcontractor of such Party’s obligations hereunder.

2.5 **Duration of Phase A.** The joint research and development activities in Phase A are scheduled for an initial term until [***]. The Parties shall discuss in good faith an extension of Phase A at the latest [***] before the end of the initial term, provided that any extension of Phase A shall require the written mutual agreement between the Parties.

2.6 **General Obligations of the Parties in Phase A.** During Phase A, each Party shall:

(a) use its Commercially Reasonable Efforts to discover, research and develop Clinical Candidates and to perform its respective activities pursuant to the Research Plan, and

(b) perform its activities under the Research Plan in good scientific manner, and in compliance with all requirements of Applicable Laws, and

(c) contribute such personnel, equipment, facilities and other resources as reasonably necessary to perform its obligations under the Research Plan and to achieve efficiently the objectives thereof, provided that each Party shall only be obliged to contribute those FTEs set forth in Section 2.3 above and in the Research Plan,

(d) provide the other Party with such materials, information and other assistance required to be provided under the Research Plan.

2.7 **Results and Reporting Under Phase A.** Each Party shall keep the other Party fully informed as to its progress, results (including without limitation the development of any technology or Program Inventions), status and plans for performing and implementing the Research Plan. Such information shall be given by periodic, informal oral reports, and by a quarterly written report, which may be in the form of a PowerPoint presentation during meetings of the Joint Research Committee, delivered not later than thirty (30) days following the end of every Calendar Quarter during which any activities are performed under the Research Plan.
2.8 Records

(a) Each Party shall maintain records (including but not limited to lab notebooks, results of experiments, study protocols and amendments, study reports, etc.), in sufficient detail and in good scientific manner (including without limitation as appropriate for patent and regulatory purposes), which shall be complete and accurate and shall fully and properly reflect all work done and results achieved in its performance of the Research Plan. All such records shall be jointly owned, with the intellectual property rights subsisting therein owned in accordance with Section 12, and copies of such records shall be made available to the other Party upon reasonable request.

(b) Upon the reasonable written request of a Party (but not more than once per calendar year), the other Party shall make such records available to the requesting Party for inspection at such other Party’s premises during normal business hours for the purpose of determining or verifying the auditing Party’s compliance with its obligations hereunder. For the purposes of such inspection, the auditing Party may request, and the audited Party shall deliver up to the auditing Party copies of relevant records described in this Section 2.8. The Parties shall bear their own costs in connection with any audit conducted pursuant to this Section 2.8.

2.9 Liability

In connection with the conduct of the Development activities, hereunder, each Party shall be responsible for, and hereby assumes, any and all risks of personal injury or property damage attributable to the negligent acts or omissions of that Party or its Affiliates or Approved Subcontractors, and their respective directors, officers, employees and agents.

2.10 Nomination of LCA Products

Each Party may at any time during Phase A propose that one or more Clinical Candidates which meet the relevant specifications defined in the Research Plan is/are nominated by the Joint Research Committee as LCA Product(s) for further preclinical and clinical development in Phase B (such proposal to be considered Selection of a Clinical Candidate for the purpose of the financial terms set forth in Exhibit 1). Upon such proposal, the Joint Research Committee will (i) review and confirm whether the proposed Clinical Candidate(s) meet the relevant specifications defined in the Research Plan, (ii) if several proposed Clinical Candidates targeting the same Target Combination meet such specifications: decide which of these Clinical Candidates is best suited for further preclinical and clinical development (Preferred Clinical Candidate), and (iii) decide whether the Preferred Clinical Candidate(s) shall be developed as LCA Product(s). The Joint Research Committee shall make the decisions according to (i) to (iii) in good faith and shall not take into consideration whether any of these decisions would trigger the payment according to Section 10.1(d). For the avoidance of doubt, if only one proposed Clinical Candidate targeting a certain Target Combination meets the relevant specifications defined in the Research Plan, such Clinical Candidate shall automatically be the Preferred Clinical Candidate for such Target Combination. If and when the Joint Research Committee decides that a Preferred Clinical Candidate shall be developed as LCA Product (as documented in the minutes of the Joint Research Committee), the Parties obligations under the Research Plan shall terminate, and Phase B shall be initiated with respect to such Preferred Clinical Candidate. For the avoidance of doubt, neither Party may propose to the Joint Research Committee a Clinical Candidate targeting a Target Combination for which a Preferred Clinical Candidate has already been selected.
2.11 **Unilateral Development.** If a Party—through the Joint Research Committee pursuant to Section 2.10—decides not to develop a Preferred Clinical Candidate as an LCA Product and move it to Phase B, this shall be regarded as an opt-out by such Party in accordance with Section 18 and the process specified in Section 18.1 and 18.3 and the terms and conditions set forth in Sections 18.4 to 18.8 shall apply mutatis mutandis. In such event, the Opt-Out Notice (as specified in Section 18.1) shall be such Party’s declaration of its decision not to develop such Preferred Clinical Candidate as an LCA Product in such Joint Research Committee meeting and the Opt-Out Date (as specified in Section 18.1) shall be the date thirty (30) days after the date of the Joint Research Committee meeting in which such Party declared its decision not to develop such Preferred Clinical Candidate as an LCA Product. If the Parties agree not to advance a certain Clinical Candidate to Phase B, then such Clinical Candidate shall be considered a Ceased Product and Section 18.4 shall apply mutatis mutandis.

2.12 **Back-Up Candidates.** Concurrently with the decision to develop a proposed Clinical Candidate as LCA Product or Unilateral Product, as applicable, the Joint Research Committee (if both Parties wish to develop such Clinical Candidate) or the Continuing Party (if only one Party wishes to develop such Clinical Candidate) shall be entitled to also designate a Back-up Clinical Candidate (if available) as Back-up Candidate for the respective Target Combination (and in such event, the Joint Research Committee or the Continuing Party, as applicable, may decide at any time that the Back-up Candidate shall replace the originally selected Clinical Candidate as LCA Product or Unilateral Product for the purposes of this Agreement).

3. **PHASE B – PRECLINICAL AND CLINICAL DEVELOPMENT**

3.1 **Goal of Phase B.** The goal of Phase B is to jointly develop on an LCA Product-by-LCA Product basis, an LCA Product in accordance with the applicable Development Plan through preclinical and clinical phase on the basis of a 50/50 cost sharing.

3.2 **Development Plans.** Without undue delay after nomination of an LCA Product, and on an LCA Product-per-LCA Product basis, the Parties shall agree on the initial Development Plan and Budget, both including without limitation clinical and manufacturing activities until Establishment of Proof of Concept, taking into consideration either Party’s capabilities and resources. Such initial Development Plan and Budget shall be endorsed by the Joint Steering Committee. Each Party may recommend changes to a Development Plan at any time; provided, however, that such changes shall be effective only upon the approval by the Joint Steering Committee.
3.3 Subcontracting During Phase B
(a) Subject to Sections 3.3(b) and 3.3(c), each Party may perform some or all of its obligations under or relating to the Development Plan through any of its Affiliates or one or more Third Parties.
(b) Notwithstanding Section 3.3(a), and subject to Section 3.3(c), neither Party may subcontract any of its obligations under the Development Plan relating to the performance of a clinical trial, the manufacture of an LCA Product or a component thereof, or the development or manufacture of a companion or other diagnostic product, without the prior approval of the Joint Steering Committee, unless such subcontractor is an Affiliate or Permitted Subcontractor (in which case no such Joint Steering Committee approval shall be required).
(c) The subcontracting Party shall ensure that: (i) any such Approved Subcontractor shall perform such subcontracted obligations pursuant to a written agreement; (ii) none of the rights of the other Party hereunder are diminished or are otherwise adversely affected as a result of such subcontracting; and (iii) the Approved Subcontractor undertakes in writing all obligations of confidentiality and non-use regarding both Parties’ Confidential Information which are substantially the same as those undertaken by the Parties hereunder. In the event that a Party performs one or more of its obligations under the Development Plan through any such Approved Subcontractor, then such Party shall at all times be responsible for the performance by such Approved Subcontractor of such Party’s obligations hereunder.

3.4 Duration of Phase B
Phase B shall begin on an LCA Product-by-LCA Product basis upon nomination of the respective LCA Product pursuant to Section 2.10 and shall end upon the earlier of (i) opt-out of a Party pursuant to Section 18 (subject to the provisions on unilateral development by the Continuing Party and on continued funding by the Opt-Out Party as set forth in Section 18), (ii) abandonment of the Phase B Development activities by mutual agreement between the Parties, (iii) completion of all Development activities for all countries in which the LCA Product shall be Commercialized, (iv) conclusion of a Joint Divestment Process, and (v) any other date specified in the applicable Development Plan.

3.5 General Obligations of the Parties in Phase B
Each Party shall:
(a) use its Commercially Reasonable Efforts to Develop the respective LCA Product during the necessary preclinical and clinical stages and to perform its respective activities pursuant to the applicable Development Plan,
(b) perform its activities under the applicable Development Plan in good scientific manner, and in compliance with all requirements of Applicable Law,
(c) contribute such personnel, equipment, facilities and other resources as reasonably necessary to perform its obligations under the applicable Development Plan and to achieve efficiently the objectives thereof, provided that each Party may only incur Shared Costs as provided in Section 10.9 and shall only be obliged to contribute those FTEs set forth in the applicable Development Plan,
refrain from using in any capacity in connection with the Development, manufacture or Commercialization of an LCA Product, any person or entity who has been debarred pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act or a similar legislation in another jurisdiction, or who is the subject of a conviction described in such section, and

(e) provide to the other Party such materials, information and other assistance required to be provided under the applicable Development Plan.

3.6 Reference to Certain Provisions of Phase A. Sections 2.7, 2.8 and 2.9 shall apply mutatis mutandis to Phase B.

3.7 Ad Hoc and Annual Updates to the Development Plan. On an annual basis, or more frequently as necessary and agreed by the Parties, but no later than by 30 September (in order for the Parties to prepare their respective budgets for the coming *** calendar years), the Joint Steering Committee shall review the Development Plan and the related Budget in order to make annual updates to the Development Plan and Budget for the then current calendar year, if any, plus the following *** calendar years both to be approved by the Joint Steering Committee. In the event that the Joint Steering Committee cannot agree on an annual update to the Development Plan and Budget, then the most recent version of the Development Plan and Budget will be deemed the Development Plan and Budget for the period, until the Parties are able to reach an agreement on any update to the Development Plan and Budget. The Parties agree that no later than *** months prior to the anticipated Establishment of Clinical Proof of Concept, the Parties, via the Joint Development Team and the Joint Steering Committee, shall agree on an update to the Development Plan, including without limitation the Budget, to cover the period after Establishment of Clinical Proof of Concept. Establishment of Clinical Proof of Concept shall be followed by Phase II Clinical Trial(s) or a Phase III Clinical Trial. Such update to the Development Plan and Budget shall form the basis of any continued Development after the Establishment of Clinical Proof of Concept by both Parties.

3.8 Preparation of IND. The Parties shall jointly be responsible via the Joint Steering Committee for producing the initial version of the proposed IND submission as well as a work plan and budget for the clinical phase of the Development of an LCA Product, including but not limited to the CMC costs. Once such an IND submission package has been agreed on by the Joint Steering Committee, this shall constitute “Proposed IND Submission” for the purposes of Section 18 and the financial terms set forth in Exhibit 1.

3.9 Third Party as Supplier. If relevant, the Joint Development Team shall determine the strategy, timing and other matters relating to identifying a Third Party to manufacture the LCA Product (or any component thereof) and shall make proposals in respect of the same to the Joint Steering Committee. In the case where, based on a proposal from the Joint Development Team, the Joint
Steering Committee elects to designate a Third Party to be responsible for manufacturing of an LCA Product (or any component thereof), one Party or both Parties, to be determined by the Joint Steering Committee, shall enter into a supply agreement with such Third Party on customary and reasonable terms and conditions. The Joint Development Team shall determine the strategy, timing and other matters relating to entering into the supply agreement. Notwithstanding the foregoing, at such time as the Joint Steering Committee determines to recruit a Third Party, the Joint Steering Committee shall determine whether to designate a Party to take the lead in negotiating and entering into the supply agreement or to allocate such responsibilities between the Parties. If one Party is designated to take the lead in negotiating such agreement, such Party shall provide the other Party with term sheets and substantive agreement drafts during the negotiations (including without limitation any proposed execution version) for review and comment and the designated Party shall not enter into any such supply agreement (or any amendment, waiver or other modification thereof) without the written approval of the other Party, which approval shall not be unreasonably withheld. No contractual or other obligations shall be entered into vis-à-vis a Third Party unless the Joint Steering Committee shall designate and authorize a Party to enter into such obligations, before such obligations have been financially covered in the Budget.

3.10 Companion Diagnostic and Biomarkers. To the extent that biomarker analysis or a companion diagnostic will be required as per the Research Plan or the Development Plan, the Joint Research Committee or the Joint Steering Committee, as applicable, will consider Biontech’s capabilities for biomarker testing and diagnostic development as well as alternative proposals and will make the decision as to whether Biontech in the sole interest of the applicable LCA Product shall be the preferred choice to determine biomarkers and develop a companion diagnostic. If Biontech is selected by the Joint Steering Committee to determine biomarkers and develop a companion diagnostic for the applicable LCA Product, Biontech will use Commercially Reasonable Efforts to develop a companion diagnostic to be tested in clinical trials and shall have the exclusive right to manufacture and commercialize such companion diagnostic. The costs incurred by Biontech in developing such a companion diagnostic shall be considered Shared Costs for the purposes of this Agreement and shall be included in the then current Budget. However, any costs incurred or profit obtained during the commercial manufacturing or commercialization of any such companion diagnostic by Biontech shall be incurred and obtained at Biontech’s sole expense and benefit, and shall not be considered Shared Costs nor Shared Profits. Notwithstanding the foregoing or any other provision in this Agreement, the Parties acknowledge and agree that Genmab has the right to appoint and enter into arrangements with [***] to develop companion or other diagnostics relating to LCA Products pursuant to and in accordance with the terms of a side letter no. 5 to the Prior Collaboration Agreement dated 12 August 2021 (as amended by amendment no. 1 to side letter no. 5 dated 23 September 2021), which is appended to this Agreement in Exhibit E, and the terms of which the Parties agree shall apply mutatis mutandis to this Agreement (with references to the Prior Collaboration Agreement therein being read as references to this Agreement).
3.11 [***] MSA. Notwithstanding the foregoing or any other provision in this Agreement, the Parties acknowledge and agree that Genmab entered into a Master Services Agreement together with Genmab B.V. and [***] ([***]) on 22 May 2017 (the [***] MSA) pursuant to which [***] performed extended target safety assessment studies (TSAs) in respect of certain Collaboration Targets, including but not limited to the antigens [***], (collectively the Agreed TSAs). Notwithstanding Section 14 of this Agreement, the Parties acknowledge and agree that each Party may freely use and disclose the Agreed TSAs for any other purpose or project outside the scope of this Agreement. For clarity, the Clinical Candidates and LCA Products in respect of which an Agreed TSA is performed and the terms of this Section 3.11 shall constitute Confidential Information and shall continue to be subject to the terms of Section 14 of this Agreement.

3.12 Joint Combination Products.

(a) The Parties acknowledge and agree that they may, [***], jointly agree in writing to research and develop Joint Combination Product(s) and this shall be reflected in the relevant Research Plan and/or Development Plan.

(b) For clarity, save to the extent expressly stated otherwise, the terms of this Agreement shall apply to any such Joint Combination Product if it includes or requires the co-administration of [***], irrespective of whether it also includes or requires the co-administration of [***] or [***]. The terms of the relevant [***] or [***] shall continue to apply in respect of the use of [***] or [***] (respectively) outside of such Joint Combination Product, including, without limitation, use of [***] or [***] in combination products that do not include [***] and any terms which may apply under [***] if [***] becomes a [***] (as such term is defined in the [***]) pursuant to [***].

(c) For the purposes of this Agreement, a Joint Combination Product shall be treated as if it were a [***], save for the purposes of Sections 4, 5, 6.8, 8, 9.4, 10.13, 11.4, 12.2, 12.5, 12.11, 12.12(e) (subject to Section 12.12(f)), 13.7 and 14.7. If any Proprietary Combination Product includes [***] included in a Joint Combination Product, the references to [***] in the terms of this Agreement relating to Proprietary Combination Products (including, without limitation, Sections 4, 5, 6.8, 8, 9.4, 10.13, 11.4, 12.2, 12.5, 12.11, 12.12(e) (subject to Section 12.12(f)), 13.7, 14.7 and Exhibit 11) shall be deemed to be references to [***] included therein and not a reference to [***].

(d) If any [***] included within a Joint Combination Product becomes [***], the terms of Exhibit 11 shall apply with respect to the treatment of such Joint Combination Product.
3.13 **Use of [***]**

(a) The Parties acknowledge and agree that, [***]:

(i) the Parties may jointly agree in writing to use [***] in conjunction with [***] at any time during the term of [***] and such use shall be included in the relevant Research Plan and/or Development Plan. For clarity, [***]; and

(ii) [***].

In each case (i) and (ii) above, the Parties acknowledge and agree that [***] shall constitute a [***] which may be used to [***] and [***] the relevant [***], [***] or [***]. Save as expressly stated otherwise, [***] shall not be considered a [***] or a [***] under the terms of this Agreement.

(b) [***]

(c) [***]

(d) [***]

3. PROPRIETARY COMBINATION PRODUCTS

4. **Proprietary Combination Products**

4.1 **General Principles** Each Party shall be entitled to pursue the [***] and [***] of Proprietary Combination Products at its own costs, subject to the terms and conditions of this Agreement, including the provisions set forth in this Section 4. For clarity, if a Proprietary Combination Product includes [***], the use of such [***] in the Proprietary Combination Product shall be subject to the terms of this Agreement relating to Proprietary Combination Products, including (without limitation) Sections 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, and 15, of this Agreement, as if it were [***], and not subject to any equivalent clauses on combination products included in the [***]. The terms of the [***] shall continue to apply in respect of the use of [***] outside of the Proprietary Combination Product (and also, for clarity, outside of any Joint Combination Product), including, without limitation, use of [***] or [***]. Any terms which may apply under [***] if [***] becomes [***] (as such term is defined in the [***]) shall also apply to the use of such [***] in any Proprietary Combination Product under this Agreement and such [***] shall become [***] as further described in Exhibit 11.

4.2 **Proprietary Combination Studies** Each Party shall be entitled to initiate and pursue [***] Proprietary Combination Studies at its own costs subject to the terms of this Agreement, including this Section 4.2.

(a) **Submission of Research Plan** Prior to the initiation of any [***] Proprietary Combination Study, the relevant Developing Party shall submit to the Non-Developing Party a draft [***] research plan at least [***] days prior to the Joint Steering Committee meeting where the Joint Steering Committee is to review such plan. The Non-Developing Party shall review and provide its feedback to the Developing Party within [***] days of receipt of such draft [***] research plan. Following consideration by the Developing Party of such feedback from the Non-Developing Party, the Developing Party shall submit such draft [***] research plan, including any updates made by the Developing Party based on the feedback from the Non-Developing Party, to the Joint Steering Committee. Such draft [***] research plan shall set forth in reasonable detail:
(i) the proposed Proprietary Combination Product,
(ii) information about the proposed [***] and, if applicable, [***] (to the extent that the Non-Developing Party does not already have access to such information) and any [***] included in the proposed Proprietary Combination Product, including the respective mechanisms of action as well as any known potential safety risks;
(iii) the rationale for selecting the proposed combination;
(iv) information as to the Developing Party’s possession of the right to [***], [***] and/or [***] (or [***], [***] and/or [***] together with [***]) the proposed [***] (whether by [***], [***] or [***]);
(v) the proposed preclinical activities, including the experimental set-up;
(vi) the volumes of [***] and, if applicable, [***], required;
(vii) anticipated timelines; and
(viii) a risk assessment on whether and how the proposed [***] Proprietary Combination Study may affect on-going activities under this Agreement, [***] or [***];

in each case (i) to (viii), to the extent reasonably necessary for the Non-Developing Party to evaluate the proposed Proprietary Combination Product and [***] Proprietary Combination Study.

In addition to the above, the Developing Party will at the same time as providing the draft [***] research plan to the Non-Developing Party also inform the Non-Developing Party if it is aware that a license of any intellectual property rights owned or controlled by [***] may be needed to [***], [***] or [***] the [***] in combination with [***] and, if applicable, [***] and/or [***].

(b) Review of Research Plan. Following submission of a [***] research plan in accordance with Section 4.2, the Non-Developing Party shall review and provide written feedback on such plan to the Developing Party within [***] days of its receipt of such plan. The Developing Party shall give reasonable consideration to the Non-Developing Party’s comments and shall also make itself reasonably available to participate in a meeting (including by video conference or teleconference) with the Non-Developing Party prior to the Joint Steering Committee meeting (if applicable) to discuss the Non-Developing Party’s comments. To the extent the Non-Developing Party reasonably requests additional information or documentation relating to the Developing Party’s possession of the right to [***], [***] and/or [***] a proposed [***] which the Developing Party [***], [***] and/or [***], the Developing Party shall provide such information or documentation for the Non-Developing Party’s review, provided that the Developing Party may redact any information [***].
(c) Approval by Joint Steering Committee. Each proposed [***] Proprietary Combination Study shall be discussed and approved by the Joint Steering Committee prior to its initiation by the Developing Party. For avoidance of doubt, the Joint Steering Committee can also decide to agree on the relevant research plan through exchange of emails without the requirement of a formal Joint Steering Committee meeting, provided, for clarity, that the review process and applicable time period set out in Section 4.2 shall continue to apply and any such decision by the Joint Steering Committee is recorded in the minutes of the next Joint Steering Committee meeting following such decision by email. Section 11.4 below shall apply with respect to the Joint Steering Committee’s review and approval of the proposed [***] Proprietary Combination Study. If the Developing Party wishes to make any material change to the research plan for such [***] Proprietary Combination Study to be conducted by the Developing Party, including any change to the research plan that may materially impact the items set out in Sections 4.2(a)(i) to 4.2(a)(viii) above, it shall seek the Joint Steering Committee’s prior approval to such change.

(d) [***] under [***]. If the [***] proposed for a Proprietary Combination Product is [***], [***] and/or [***], the Parties shall jointly agree in good faith to which extent any Confidential Information [***] will be shared [***].

(e) Conduct of [***] Proprietary Combination Study. Following the Joint Steering Committee’s approval of the proposed research plan, the Developing Party shall be solely responsible for the conduct of the relevant [***] Proprietary Combination Study and shall bear all related costs[***]. Any such [***] Proprietary Combination Study shall be conducted in good scientific manner and in accordance with all requirements of Applicable Law, including in relation to maintenance of records and data.

(f) Reporting on [***] Proprietary Combination Study. The Developing Party will keep the Non-Developing Party reasonably informed on its activities in relation to such [***] Proprietary Combination Study and shall share data relevant for the evaluation of [***] as part of the Proprietary Combination Product from such [***] Proprietary Combination Study with the Non-Developing Party (i) at least on a quarterly basis during the Parties’ Joint Development Team meetings, and (ii) on a quarterly basis during the Parties’ Joint Steering Committee meetings. The Developing Party shall as soon as reasonably practicable provide the Non-Developing Party with any updates (non-material as well as material) to the research plan for such [***] Proprietary Combination Study.
(g) **Out-licensing of [***]** If the Developing Party out-licenses its right to [***] of any Proprietary Combination Product to [***] following the approval of the relevant [***] Proprietary Combination Study by the Joint Steering Committee, the following shall apply:

(i) the Developing Party shall have the right to continue to conduct and complete such [***] Proprietary Combination Study, provided that the Developing Party retains the required licenses to [***] to complete such [***] Proprietary Combination Study in compliance with the terms of this Agreement and uses its best efforts to ensure [***] compliance with the terms of this Agreement relating to such [***] Proprietary Combination Study, including with respect to reporting, intellectual property rights and publication;

(ii) any material change to the research plan for such [***] Proprietary Combination Study to be conducted by the Developing Party, including any change to the research plan that may materially impact the items set out in Sections 4.2(a)(i) to 4.2(a)(viii) above, shall require the approval of the Joint Steering Committee; and

(iii) the Developing Party shall only share with [***] any information or data solely relating to [***] included in such Proprietary Combination Product (x) upon prior approval of the Joint Steering Committee (which shall not be unreasonably withheld or delayed), and (y) after [***] has agreed to confidentiality obligations consistent with those set forth in Section 14.

(h) **Confirmation of Approval of Certain [***] Proprietary Combination Studies** The Parties hereby confirm the Joint Steering Committee’s approval of [***]. Further, the Parties hereby confirm the Joint Steering Committee’s approval of [***].

4.3 [***] Proprietary Combination Studies.

(a) **Initiation of [***] Proprietary Combination Studies** Following the successful completion of any [***] Proprietary Combination Study in relation to any proposed Proprietary Combination Product, or if no [***] Proprietary Combination Study is required by the relevant Regulatory Authority prior to initiating a [***] Proprietary Combination Study for such proposed Proprietary Combination Product, each Party shall be entitled to initiate and pursue [***] Proprietary Combination Studies in relation to such Proprietary Combination Product subject to the terms of this Agreement, including this Section 4.3.

(b) **Submission of Study Request** Prior to the initiation of any [***] Proprietary Combination Study, the relevant Developing Party shall submit to the Non-Developing Party a request to initiate such [***] Proprietary Combination Study at least [***] days prior to the Joint Steering Committee meeting where the review of such request will be on the agenda. The Non-Developing Party shall review and provide written feedback on such request to the Developing Party.
Party within [***] days of its receipt of such request. The Developing Party shall give reasonable consideration to the Non-Developing Party’s comments and shall also make itself reasonably available to participate in a meeting (including by video conference or teleconference) with the Non-Developing Party prior to the Joint Steering Committee meeting to discuss the Non-Developing Party’s comments. Following such consideration by the Developing Party of the feedback provided by the Non-Developing Party, the Developing Party shall submit such request (including any updates made by the Developing Party based on the feedback provided by the Non-Developing Party) to the Joint Steering Committee. Such request shall include the following support data and documentation:

(i) all relevant data relating to [***] or, if applicable, [***] (to the extent that the Non-Developing Party does not already have access to such information) and [***], or the proposed Proprietary Combination Product generated outside of the activities under this Agreement or [***] or [***], in each case which is in the possession of the Developing Party (including relevant data from the [***] Proprietary Combination Study or any other [***] research activities);

(ii) draft of an initial [***] plan describing the [***] Proprietary Combination Study activities and manufacturing requirements related to [***] forming part of the Proprietary Combination Product and also containing the information set out in Section 4.3(c) below;

(iii) a [***] for the [***] Proprietary Combination Study for which the Developing Party is seeking the JSC’s approval;

(iv) the volumes of [***] and, if applicable, [***], required;

(v) anticipated timelines;

(vi) a risk assessment on whether and how the proposed [***] Proprietary Combination Study may affect on-going activities under this Agreement, [***] or [***], including without limitation information about any potential overlapping toxicity profiles of the products included in the Proprietary Combination Product;

(vii) information regarding any intellectual property rights owned or controlled by [***] of which the Developing Party is aware where a license to such intellectual property rights may be needed to [***], [***] or [***] the [***] in combination with [***] and, if applicable, [***] and/or [***]; and

(viii) any other information set forth in Section 4.2(a) to the extent that has not already been provided as part of the process set forth in Section 4.2;

in each case (i) to (viii), to the extent reasonably necessary for the Non-Developing Party to evaluate the proposed [***] Proprietary Combination Study.
(c) **Procedure and Joint Steering Committee Approval.** Following the submission of the documents and data in accordance with Section 4.3(b), the procedure set forth in the provisions of Sections 4.2(b) to 4.2(d) shall apply mutatis mutandis. Once a [***] Proprietary Combination Study has been approved by the Joint Steering Committee, the Developing Party may initiate and pursue such [***] Proprietary Combination Study in accordance with the submitted initial [***] plan pursuant to Section 4.3(b)(ii) (the **Proprietary Combination Plan**). Such Proprietary Combination [***] Plan shall include an outline of [***] and [***] and [***] activities that the Developing Party considers necessary for the [***] of the Proprietary Combination Product up to and including [***] for such Proprietary Combination Product. For clarity, approval by the Joint Steering Committee of a proposed [***] Proprietary Combination Study does not include approval of any additional [***] Proprietary Combination Study described in such outline, unless [***] for such [***] Proprietary Combination Study is provided pursuant to Section 4.3(b)(iii) and approved by the Joint Steering Committee. If the Developing Party wishes to make any material change to such Proprietary Combination [***] Plan or [***], including any change that may have a material impact on the items set out in Section 4.3(b)(iv) to (vi), or to [***] referred to in Section 4.3(b)(iii), it shall seek the Joint Steering Committee’s prior approval to making such change.

(d) **Conduct of [***] Proprietary Combination Study.** Following the Joint Steering Committee’s approval of the proposed [***] Proprietary Combination Study, the Developing Party shall be solely responsible for the conduct of the relevant [***] Proprietary Combination Study and shall bear all related costs, [***]. The Non-Developing Party will reasonably support the Developing Party in such [***] Proprietary Combination Study, including by providing access to all relevant information on the [***] for [***] and [***] in connection with the [***] Proprietary Combination Study. [***] The Developing Party shall perform the [***] Proprietary Combination Study in accordance with all requirements of Applicable Law, including [***] of competent Regulatory Authorities, including in relation to maintenance of records and data. Notwithstanding anything to the contrary in this Agreement, the Developing Party shall not be authorized to initiate any [***] for a Proprietary Combination Product [***] until the Parties have entered into the Commercialization Agreement referred to in Section 6.5 of this Agreement covering commercialization of [***] included in such Proprietary Combination Product.

(e) **Reporting to Joint Steering Committee; Final Study Report.** The Developing Party will keep the Non-Developing Party reasonably informed, at least on a quarterly basis, on its activities in relation to such [***] Proprietary Combination Study and shall report all relevant information and data on the use and performance of [***] as well as the Proprietary Combination Product to the Joint Steering Committee, including information on any safety issues relating to [***] and/or Proprietary Combination Product. The Developing Party shall as soon as reasonably practicable provide the Non-Developing Party with any updates (non-material as well as material) to the Proprietary Combination [***] Plan and/or [***] for such Proprietary Combination Study. Promptly following completion [***] of the [***] Proprietary
Combination Study, the Developing Party shall provide the Non-Developing Party with an electronic draft of the final study report which shall include a complete copy of the ***Proprietary Combination Study data ***. However, the Developing Party shall not be obliged to disclose to the Non-Developing Party or the Joint Steering Committee any information or data (i) *** or (ii) ***. The Non-Developing Party shall have *** days after receipt of such electronic draft to provide comments regarding the ***Proprietary Combination Study. The Developing Party shall consider in good faith any comments provided by the Non-Developing Party on the draft final study report. In addition, the Developing Party shall provide to the Non-Developing Party an overview of the volumes of *** used for the completed Proprietary Combination Study *** and the associated *** costs.

(f) *** Review. The Developing Party shall provide a copy of *** for the Proprietary Combination Study that relate to the Proprietary Combination Product at least *** weeks prior to any submission thereof to *** and take any comments from the Non-Developing Party into good faith, provided that such comments are provided to the Developing Party within *** weeks after the Non-Developing Party’s receipt of the ***. Further, the Developing Party shall provide copies of any subsequent amendments to *** for the Proprietary Combination Study at least *** Business Days prior to any submission thereof to *** and take any comments from the Non-Developing Party into good faith consideration, provided that such comments are provided to the Developing Party within *** Business Days after the Non-Developing Party’s receipt of the planned amendment. The Parties acknowledge and agree that the Developing Party may redact any sensitive information relating to *** included in any *** for a Proprietary Combination Study or any amendments thereto prior to the provision of such *** or amendment to the Non-Developing Party pursuant to this Section 4.3(f), provided, however, that such redaction does not materially hamper the Non-Developing Party’s ability to assess whether the *** or *** amendment is aligned with the study request documentation and data provided pursuant to Section 4.3(b). If the Non-Developing Party reasonably believes that certain redactions materially hamper such assessment, and the Developing Party upon the Non-Developing Party’s request does not disclose such redacted information, the Non-Developing Party shall have the right to reject the submission of the *** or *** amendment.

(g) Out-licensing of ***. If the Developing Party out-licenses its right to *** of any Proprietary Combination Product to *** following the approval of the relevant ***Proprietary Combination Study by the Joint Steering Committee, the following shall apply:

(i) the Developing Party shall *** and use its best efforts to ensure *** compliance with the terms of this Agreement relating to such *** Proprietary Combination Study, including with respect to reporting, intellectual property rights and publication;
any material change to the Proprietary Combination [***] Plan or [***] for such [***] Proprietary Combination Study involving such [***] to be conducted by the Developing Party, including any change to the Proprietary Combination [***] Plan or [***] that may materially impact the items set out in Sections 4.3(b)(i)-4.3(b)(viii) above requires the approval of the Joint Steering Committee;

(iii) [***] shall be allowed to conduct further [***] Proprietary Combination Studies subject to the approval of the Joint Steering Committee pursuant to Section 4.3, and subject to a written supply agreement between Biontech, Genmab and [***] setting forth the detailed terms and conditions for such Proprietary Combination Studies; and

(iv) the Developing Party shall only share with [***] any information or data solely relating to [***] included in such Proprietary Combination Product (x) upon prior approval of the Joint Steering Committee (which shall not be unreasonably withheld or delayed), and (y) after [***] has agreed to confidentiality obligations consistent with those set forth in Section 14.

(b) Ownership and Use of Study Data. Subject to the intellectual property provisions of this Agreement, as between the Parties, all study data of any (i) or (ii) Proprietary Combination Study shall be owned by [***]. [***] hereby grants to [***] a non-exclusive, fully paid-up, worldwide license to use such study data for the development, manufacturing and commercialization of [***] and, if applicable, [***] included in the Proprietary Combination Product [***] within the framework of this Agreement or [***] or [***], if applicable, including the right to cross-reference such data for any regulatory purposes, provided that any such use is in accordance with the provisions of this Agreement, [***] and [***]. Such license shall be sublicensable in the same way as the licenses granted under Sections 12.3 or 12.4 of this Agreement and may only be transferred or assigned in accordance with Section 20.6 of this Agreement.

(i) Data Sharing Agreement. Upon the reasonable request of either Party, the Parties will negotiate in good faith and enter into a data sharing agreement relating to the Proprietary Combination Study data.

5. MANUFACTURING IN RELATION TO COMBINATION STUDIES

5.1 Supply of [***] for Proprietary Combination Studies. The Parties agree that they will supply to the Developing Party, or procure the supply of, all [***] required by the Developing Party for the conduct of any Proprietary Combination Study approved by the Joint Steering Committee pursuant to Sections 4.2 or 4.3, provided that such supply does not cause any delays or other shortfalls for the supply of [***] for the clinical development programs conducted by the Parties under this Agreement or [***]. The Parties agree that in the event of any supply or capacity shortages, any [***] shall be supplied in the following order of priority: (i) for use in [***] (including,
without limitation, any Joint Combination Product which is commercialized; (ii) for use in any Proprietary Combination Product which is commercialized; (iii) for use in the development of \([***]\) (including, without limitation, any Joint Combination Product) under this Agreement or \(\text{[***]}\) and (iv) in the use the development of any Proprietary Combination Product under this Agreement (or an equivalent combination under \(\text{[***]}\)). If various Proprietary Combination Studies under this Agreement or equivalent proprietary combination studies under \(\text{[***]}\) are proposed or run in parallel, the prioritization of \(\text{[***]}\) supply shall be discussed in the Joint Steering Committee and shall be decided by the Joint Steering Committee on the basis of (a) the scientific merit of the proposed Proprietary Combination Studies (or equivalent proprietary combination studies under \(\text{[***]}\)), (b) the market opportunity for \(\text{[***]}\)(i.e. which Proprietary Combination Product (or equivalent proprietary combination product under \(\text{[***]}\)) provides the greatest potential commercial value to \(\text{[***]}\)), and (c) if the Joint Steering Committee cannot mutually agree on the prioritization, a “first in time” principle relating to the approval of the Joint Steering Committee for each Proprietary Combination Study or equivalent proprietary combination studies under \(\text{[***]}\) (i.e. the proprietary combination study that was approved earlier shall have priority over any proprietary combination study that was approved later by the Joint Steering Committee). The Parties acknowledge and agree that, if applicable, \(\text{[***]}\) shall be manufactured and supplied to the Developing Party in accordance with the terms of \(\text{[***]}\).

5.2 **Supply Price for Proprietary Combination Studies, \(\text{[***]}\)**

5.3 **Other Manufacturing Costs.** All other costs in connection with the manufacturing and/or supply of the Proprietary Combination Products for any Proprietary Combination Study shall be borne by the Developing Party.

5.4 **Clinical Supply Agreement, QAA.** To the extent reasonably requested by either Party, the Parties will conclude a separate clinical supply agreement and/or quality assurance agreement to govern the clinical supply of \(\text{[***]}\) for the purposes of Proprietary Combination Studies. Any such separate clinical supply agreement and/or quality assurance agreement shall be in accordance with the terms and conditions of this Agreement. The Parties acknowledge and agree that, if applicable, the Parties shall conclude a separate clinical supply agreement and/or quality assurance agreement to govern the clinical supply of \(\text{[***]}\) in accordance with the terms of \(\text{[***]}\).

5.5 **Alternative Supply.** Upon reasonable request by either Party, the Joint Steering Committee shall discuss and may (at the Joint Steering Committee’s discretion) agree to establish a second source of supply of \(\text{[***]}\) from either Party or a Third Party contract manufacturer acceptable to both Parties, including with respect to reliability, quality, technical capability, financial capability and creditworthiness. The Parties acknowledge and agree that, if applicable, the Parties may agree to establish a second source of supply of \(\text{[***]}\) in accordance with the terms of \(\text{[***]}\).
6. COMMERCIALIZATION

6.1 General. The Parties agree to jointly Commercialize LCA Products and share equally all Commercialization expenses (as further defined in the Commercialization Agreement) and Profits.

6.2 Strategy and Commercialization Plans. The Joint Commercialization Committee shall decide on an overall Commercialization strategy (including without limitation the overall marketing and pricing strategy), which shall be submitted to the Joint Steering Committee for endorsement. The Parties shall in due time during Phase B but no later than [***] days after the initiation of the first Phase III Clinical Trial, on an LCA Product-by-LCA Product basis, agree through the Joint Commercialization Committee on an initial Commercialization Plan, such plan also to be submitted to endorsement to the Joint Steering Committee. Each Party may recommend changes to a Commercialization Plan at any time, provided, however, that such changes shall be effective only upon the approval by the competent Joint Commercialization Committee and the Joint Steering Committee. The Joint Commercialization Committee shall be authorized to execute any activities or decisions with regard to the Commercialization Plan, provided that such activities or decisions are within the latest Commercialization Plan as endorsed by the Joint Steering Committee. The Parties shall instruct their representatives in the Joint Commercialization Committee to use reasonable efforts to reach consensus on matters under the governance and decision-authority of the Joint Commercialization Committee.

6.3 Lead Commercialization Party. At least [***] months prior to the anticipated start of any Phase III Clinical Trial that may be used for BLA filing to a Regulatory Authority, the Parties will agree as part of the Commercialization Agreement on which Party will become Lead Commercialization Party for which Region. Within the framework of the overall Commercialization strategy, cf. Section 6.2 above, the Lead Commercialization Party shall be responsible for setting-up and operating the distribution network in its Region, including, but not limited to, the following: warehousing and distribution logistics, supply and packaging, invoicing and collection, preparing of marketing materials, handling reimbursement issues as well arranging for medical affairs functions to support the commercial endeavors in such Region. The Lead Commercialization Party shall in addition be responsible for preparing, supervising, implementing and adapting the regional marketing strategy for the relevant Region in compliance with the overall marketing strategy as approved by the relevant Joint Commercialization Committee and endorsed by the Joint Steering Committee pursuant to Section 6.2. Regional marketing strategy includes, but is not limited to, key opinion leader development, pre-launch advisory board meetings, primary market research with customers, health economic and reimbursement studies, local customary discounts, local advertising strategy, competitor analysis, un-met need analysis, local product positioning, other promotional strategies (such as sampling, give-away items, PR) and prescribing guideline inclusion. Notwithstanding the above, unless otherwise agreed in the Commercialization Agreement, the Parties agree that Genmab shall book worldwide sales.
6.4 Co-Promotion. Notwithstanding the existence of a Lead Commercialization Party for each Region, both Parties may utilize their sales representatives on a 50/50 basis to co-promote LCA Products in any Region pursuant to the provisions of the Commercialization Agreement.

6.5 Commercialization Agreement. The Parties shall negotiate in good faith and enter into a separate global commercialization agreement (the "Commercialization Agreement") at least [***] months prior to the anticipated start of any Phase III Clinical Trial that may be used for BLA filing to a Regulatory Authority, which shall be consistent with the applicable provisions of this Agreement, reflect any mechanism or structure agreed upon by the Joint Steering Committee and shall include customary provisions relating to joint Commercialization, including, among others, the following matters: amendment to and updates of the Commercialization Plan, report and audit rights, co-promotion (including, among others, performance metrics, sales force compensation strategies, division of the applicable Region between the Parties' respective sales forces on a 50/50 basis, sales force training), co-branding, marketing, recalls and medical inquiries, commercialization expenses, further details on the calculation of Profits, labeling, public statements and other information concerning the LCA Product, liability, indemnification, use of subcontractors and the responsibilities and powers of the Joint Commercialization Committee and the Lead Commercialization Party. No patient may be enrolled or randomized in such Phase III Clinical Trial before such Commercialization Agreement has been agreed by the Parties and fully executed, unless otherwise agreed by the Parties in writing.

6.6 General Commercialization Obligations. During the Commercialization phase, each Party shall

(a) use its Commercially Reasonable Efforts to Commercialize the LCA Products and to perform its respective activities pursuant to the applicable Commercialization Plan and Commercialization Agreement, as applicable, and in accordance with all Applicable Laws, including without limitation GxPs;

(b) contribute such personnel, equipment, facilities and other resources as reasonably necessary to perform its obligations under the applicable Commercialization Plan and to achieve efficiently the objectives thereof; and

(c) provide to the other Party such materials, information and other assistance required to be provided under the applicable Commercialization Plan.

6.7 Partnership Agreements. If an LCA Product is planned by the Joint Commercialization Committee to be Commercialized wholly or partly through Partnership Agreements, unless expressly set forth otherwise in the applicable Commercialization Plan, the following principles shall apply:
(a) Each Party shall use Commercially Reasonable Efforts to identify Third Parties which may be interested in concluding a Partnership Agreement and shall disclose such Third Parties to the other Party for further evaluation and discussion.

(b) Unless otherwise agreed, the Lead Commercialization Party for the Region to which the potential Partnership Agreement pertains shall be responsible for initiating and engaging in discussions with the potential Third Party Collaborator (including without limitation all business and scientific meetings) and for negotiating the respective Partnership Agreement, provided that such Party shall (i) keep the other Party at all times fully informed as to the status of any discussions or negotiations with the potential Third Party Collaborator, (ii) notify the other Party reasonably in advance of any meetings (whether in person, per telephone or otherwise) with the potential Third Party Collaborator and the other Party shall have the right (but not the obligation) to attend and participate in all such meetings, (iii) closely cooperate with the other Party in the preparation and negotiation of the Partnership Agreement (and any term sheets or similar documents relating to such Partnership Agreement), (iv) promptly provide the other Party with copies of all relevant drafts and mark-ups of the Partnership Agreement (or any term sheets or similar documents relating to such Partnership Agreement) that are exchanged in the course of the negotiations, and (v) consult with the other Party as to the terms of the Partnership Agreement (or any term sheets or similar documents relating to such Partnership Agreement) and incorporate any reasonable suggestions or requirements.

(c) No Partnership Agreement may be executed without the approval of both Parties (such approval not to be unreasonably withheld).

6.8 Commercialization of Proprietary Combination Products. The Parties shall jointly Commercialize [***] that forms part of a Proprietary Combination Product in accordance with the Parties’ overall Commercialization strategy pursuant to Section 6.2 and the Commercialization Agreement pursuant to Section 6.5. If the Proprietary Combination Product includes [***] or [***], the Parties shall commercialize such [***] or [***] in accordance with the Parties’ commercialization strategies under, and pursuant to the terms of, [***] or [***]. For avoidance of doubt, as between the Parties, the Developing Party shall be solely responsible for all aspects of the commercialization of [***], provided that the Developing Party shall use Commercially Reasonable Efforts to take the interests of the Parties under this Agreement or [***] or [***] into good faith consideration when commercializing [***]. If and to the extent mutually agreed between the Parties, and in each case solely to the extent permissible under Applicable Laws, the Parties may plan and exercise a mutual process to be agreed upon in a separate agreement for the coordination of commercialization activities of the Proprietary Combination Product, provided that the Parties shall not be under any obligation to enter into any such agreement.

42 of 122
7. REGULATORY MATTERS

7.1 General
(a) The Joint Steering Committee shall be responsible for approving the overall regulatory strategy outlined in any Development Plan and for overseeing its implementation. The Joint Development Team shall be responsible for monitoring, coordinating and implementing the actions of the Parties, in particular the design of any Phase III Clinical Trial intended to support Marketing Approval in the Major Market Countries. Unless otherwise agreed by the Joint Steering Committee, Genmab shall be the Lead Regulatory Party for the Territory for all LCA Products. Unless otherwise agreed by the Joint Steering Committee, the Lead Regulatory Party shall be responsible for all regulatory actions, communications and filings and submissions to, all applicable Regulatory Authorities with respect to a given LCA Product.

(b) Unless otherwise agreed by the Joint Steering Committee, the Lead Regulatory Party shall be named “Sponsor” of the regulatory filing as per 21 CFR 312.3 (Part B) and/or 21 CFR 312.50 in the USA, or similar rules and regulations in other jurisdictions, with respect to a given LCA Product. The Parties will work together to transfer and assign all regulatory documents, contracts, materials and information that relates to an LCA Product to the Lead Regulatory Party or its designees to the extent necessary for the Lead Regulatory Party to assume such role.

7.2 Ownership of Marketing Approvals. Unless otherwise proposed by the Joint Development Team and approved by the Joint Steering Committee, the Lead Regulatory Party shall own all INDs, BLAs and other Marketing Approvals for an LCA Product (but, for the avoidance of doubt, all dossiers submitted to any Regulatory Authority and all data and information contained therein shall be jointly owned by the Parties with the intellectual property rights subsisting therein owned in accordance with Section 12). The Lead Regulatory Party shall promptly provide a letter of reference with respect to such Marketing Approvals (including INDs and BLAs) to the other Party as may be reasonably necessary to enable such other Party to fulfill its research, Development and Commercialization obligations or perform its Commercialization rights hereunder.

7.3 Regulatory Coordination
(a) Responsibilities of Lead Regulatory Party. Subject to oversight by the Joint Steering Committee, the Lead Regulatory Party shall oversee, monitor, coordinate and effect all regulatory actions, communications and filings with, and submissions to, all applicable Regulatory Authorities with respect to an LCA Product. The Lead Regulatory Party shall also be responsible for interfacing, corresponding and meeting with the applicable Regulatory Authorities with respect to an LCA Product. Unless the Parties agree otherwise, the Lead Regulatory Party will use its Commercially Reasonable Efforts to include up to two (2) representatives of the other Party in all meetings and material telephone discussions between representatives of the Lead Regulatory Party and such Regulatory Authority related to an LCA Product.
(b) **Review of Correspondence.** The Lead Regulatory Party shall regularly inform the other Party of its current and planned regulatory activities and shall provide the other Party with drafts of any material documents and other material correspondence to be submitted to a Regulatory Authority pertaining to an LCA Product, sufficiently in advance of submission so that the other Party may review and comment on such documents or other correspondence and have a reasonable opportunity to influence the substance of such submissions. The Lead Regulatory Party shall promptly provide the other Party with copies of any material documents or other material correspondence received from or submitted to a Regulatory Authority pertaining to an LCA Product.

7.4 **Assistance.** Each Party shall cooperate with the other Party to provide all reasonable assistance, and take all actions reasonably requested by such other Party, that are reasonably necessary to enable such other Party to comply with any regulatory requirements under Applicable Law with respect to each LCA Product, including (a) obtaining and maintaining Marketing Approvals, (b) submitting annual reports, (c) performing pharmacovigilance activities and (d) sharing any relevant regulatory intelligence. Such assistance and actions shall include, among other things, notifying the other Party within [***] hours of any information it receives from a Regulatory Authority which (i) raises any material concerns regarding the safety or efficacy of the LCA Product, (ii) indicates or suggests a potential material liability for either Party to Third Parties arising in connection with the LCA Product or (iii) is reasonably likely to lead to a clinical hold, recall or market withdrawal of the LCA Product.

7.5 **Adverse Events relating to LCA Products or Unilateral Products.**

(a) **Reporting to Government Authorities.** Each Party shall, and shall cause its respective Affiliates to, furnish timely notice as required by Applicable Law (i.e., currently not later than [***] calendar days for deaths and immediately life threatening Adverse Events and not later than [***] calendar days for Serious Adverse Events) to all competent governmental agencies in those parts of the Territory in which it is the Lead Regulatory Party of all Adverse Events identified or suspected with respect to any LCA Products administered, distributed, marketed and sold under authority of any IND or Marketing Approval. Each Party shall provide the other Party with all necessary assistance in complying with all Adverse Event reporting requirements established by, or required under, any applicable IND and/or Marketing Approval in the Territory. In particular, each Party shall provide the other with timely information, in accordance with the time frames set forth below, on any Serious Adverse Events relating to any LCA Product to the extent that such Serious Adverse Events could affect the Marketing Approval(s) for the LCA Product, or relate to the safety, efficacy or potency of the LCA Product. The Parties agree that with regards to the Unilateral Products, the obligations set forth in this Section 7.5(a) shall only apply to the Continuing Party.
(b) **Reporting to Other Party.** Each Party shall, and shall cause its respective Affiliates to, furnish the other Party written notice of all Serious Adverse Events regarding any LCA Product reported to such Party or its Affiliates. Each Party shall also use its Commercially Reasonable Efforts to obtain, and to furnish to the other Party hereto, reasonably sufficient information relating to such Serious Adverse Event in order to permit that other Party to evaluate such Serious Adverse Events of the LCA Product, including, but not limited to, information about the affected patients, the circumstances surrounding the Serious Adverse Events, the consequences thereof and the sources of information. Each Party shall retain all documents, reports, studies and other materials relating to any and all such Serious Adverse Events, as the case may be. Upon reasonable written notice, each Party shall permit the other Party hereto to inspect, and to make copies of, all such documents, reports, studies and other materials, subject to all Applicable Laws regarding patient confidentiality, data protection and privacy and the terms of the Data Protection Agreement. The Parties agree that with regards to the Unilateral Products, the obligations set forth in this Section 7.5(b) shall only apply to the Continuing Party.

(c) **Pharmacovigilance Agreement.** Without limiting the generality of the foregoing, no later than [***] months prior to the anticipated filing of the first IND for an LCA Product, the Parties shall enter into a pharmacovigilance agreement detailing each Party’s pharmacovigilance responsibilities in connection with the LCA Product. The pharmacovigilance agreement will prevail in case of discrepancy with the provisions set forth in sub-sections (a) and (b) above with regards to LCA Products.

### 7.6 Audit for Compliance with Applicable Laws

For the Term and for a period of [***] years thereafter:

(a) each Party shall keep and maintain, and shall require its Affiliates to keep and maintain, accurate and complete copies of all books and records that are necessary or reasonably useful to demonstrate that all activities performed by such Party in connection with its research, Development and Commercialization of Clinical Candidates and LCA Products [***] under this Agreement comply with Applicable Laws related to transparency reporting requirements, anti-bribery and anti-corruption, and

(b) upon reasonable written request of a Party, the other Party shall make such books and records available to the requesting Party for inspection at such other Party’s premises during normal business hours for the purpose of the requesting Party verifying the other Party and/or its Affiliates’ compliance with: (i) all Applicable Laws in connection with the performance of its activities under this Agreement, and/or (ii) the terms of Section 7.7 below. The inspecting Party shall provide the other Party with at least [***] days prior written notice of such inspection (or such shorter notice period as
required to allow the inspecting Party to comply with Applicable Laws and/or the request of a Regulatory Authority). A Party may only exercise such audit right once per calendar year, save that it may perform additional audits in the same calendar year for cause. For the purposes of this Section 7.6, “for cause” may include without limitation: (i) to respond to a request or query from a Regulatory Authority; or (ii) if the last inspection identified non-compliance by the other Party. For the purposes of such inspection, the auditing Party may request, and the audited Party shall deliver up to the auditing Party, copies of relevant books and records described in this Section 7.6. Subject to Section 14.1, each Party agrees that all information made available to it in accordance with this Section 7.6 shall be Confidential Information of the Disclosing Party, and further agrees to hold in strict confidence all such information. The Parties shall bear their own costs in connection with any audit conducted pursuant to this Section 7.6.

7.7 **Anti-Bribery and Anti-Corruption**. Each Party:

(a) represents and warrants that, as at the Execution Date, it has in place its own policies and procedures, including but not limited to a code of conduct, compliance training provided to employees on a frequent basis and internal approval processes for payments, to ensure its and its Affiliates’ compliance with Applicable Laws relating to anti-bribery and anti-corruption in connection with activities performed under this Agreement. From the Execution Date and for the duration of the Term thereafter, each Party shall maintain and enforce such policies and procedures in connection with the activities performed under this Agreement.

(b) shall ensure that, from the Execution Date and for the duration of the Term thereafter, any of its agents, consultants, contractors, subcontractors or other persons engaged in the performance of such Party’s obligations under this Agreement do so only on the basis of a written contract which imposes on and secures from such person obligations to comply with such Applicable Laws relating to anti-bribery and anti-corruption.

8. **REGULATORY MATTERS RELATING TO PROPRIETARY COMBINATION PRODUCTS**

8.1 **General**. The Developing Party shall be solely responsible, at its own cost, for all regulatory matters in relation to the Proprietary Combination Product and [***], provided that all regulatory filings or submissions to be made relating to [***] shall require the Non-Developing Party’s prior written approval (which shall not be unreasonably withheld or delayed). [***] The Parties envisage that the Marketing Approval for [***] included in the Proprietary Combination Product will be obtained before the Marketing Approval for the Proprietary Combination Product can be obtained. If, however, the Developing Party may be able to obtain Marketing Approval of the Proprietary Combination Product before [***] has obtained a Marketing Approval for [***], the Joint Steering Committee shall discuss and may agree on any necessary amendments to the regulatory strategy for [***]. For clarity, the Parties agree that the Developing Party shall not be allowed to file an
application for Marketing Approval of the Proprietary Combination Product for any Indication where [***] has not yet obtained Marketing Approval, unless otherwise approved by the Non-Developing Party in accordance with the first sentence of this Section 8.1. The Developing Party shall: (a) [***]; and (b) [***]. The Developing Party will use its reasonable efforts to include at least [***] representative of the Non-Developing Party in all meetings and other material discussions (whether by video conference, teleconference or other communication) with a Regulatory Authority regarding matters related to [***].

8.2 Right of Reference, Further Assistance. The Developing Party shall be allowed to reference any regulatory filings or submissions made, or any regulatory approvals obtained, by the Parties pursuant to this Agreement or [***] (or, if applicable, [***]) in relation to [***] included in the Proprietary Combination Product. In addition, the Non-Developing Party will reasonably cooperate with the Developing Party to provide all reasonable assistance and take all actions reasonably requested by the Developing Party at the Developing Party’s cost that are reasonably necessary to enable such Party to comply with any regulatory requirements under Applicable Law with respect to the Proprietary Combination Product to the extent such requirements relate to [***] included in the Proprietary Combination Product.

8.3 Adverse Events/Safety.

(a) Reporting to Non-Developing Party. Unless otherwise provided for in the pharmacovigilance agreement between the Parties, the Developing Party shall, and shall cause its respective Affiliates to, furnish the Non-Developing Party written notice of all Serious Adverse Events regarding any Proprietary Combination Product. The Developing Party shall also use its Commercially Reasonable Efforts to obtain, and to furnish to the Non-Developing Party, such information reasonably sufficient to permit that Non-Developing Party to evaluate such Serious Adverse Events in relation to [***] included in the Proprietary Combination Product, including, but not limited to, information about the affected patients, the circumstances surrounding the Serious Adverse Events, the consequences thereof and the sources of information. The Developing Party shall retain all documents, reports, studies and other materials relating to any and all such Serious Adverse Events. Upon reasonable written notice, the Non-Developing Party shall permit the Non-Developing Party to inspect, and to make copies of, all such documents, reports, studies and other materials, subject to all Applicable Laws regarding patient confidentiality, data protection and privacy.

(b) Pharmacovigilance Agreement. Unless otherwise agreed between the Parties, the existing pharmacovigilance agreement between the Parties detailing each Party’s pharmacovigilance responsibilities shall also apply with respect to the Developing Party’s conduct of any [***] Proprietary Combination Study. Upon the request of either Party, the Parties shall negotiate in good faith an amendment to the existing pharmacovigilance agreement or a new pharmacovigilance agreement relating to Proprietary Combination Studies.
The pharmacovigilance agreement(s) will prevail in case of discrepancy with the provisions set forth in sub-section (a) above.

9. EXCLUSIVITY

10. FINANCIAL PROVISIONS

10.1 Upfront Payment. As consideration for entering into this Agreement and contributing Biontech’s Technology and the existing projects to the collaboration hereunder, Genmab shall pay to Biontech the following non-refundable upfront payments:

(a) Ten million US dollars ($10,000,000) within [***] weeks of the Effective Date; and

(b) One million US dollars ($1,000,000) within [***] weeks following agreement by the Parties that at least one of the antibodies in the current available panel as attached hereto in Exhibit 4 targeting [***] that are not covered by the claims in the relevant third party patents identified by the Parties prior to the Effective Date; and

(c) One million US dollars ($1,000,000) within [***] weeks following the conclusion by the Parties that at least one of the antibodies in the current available panel as attached hereto in Exhibit 4 is non-agonistic. Agonistic [***] antibodies are defined to be able to activate the [***] signaling by binding to the [***], which is physiologically expressed on T-cells. Agonistic anti-[***] without further need for [***]. For the avoidance of doubt, the decision on which and how many of the antibodies of the panel in Exhibit 4 will be tested for being non-agonistic will be made by the Joint Research Committee.

(d) Three million US dollars ($3,000,000) within [***] weeks following the date on which the Joint Research Committee for the first time and in accordance with Section 2.10 (as documented by the minutes of the Joint Research Committee) selects a Preferred Clinical Candidate which wholly or partly is derived from [***] developed by or on behalf of Biontech, and such Preferred Clinical Candidate is either (i) advanced to an LCA Product pursuant to Section 2.10 or a Unilateral Product (whether a Genmab Unilateral Product or a Biontech Unilateral Product) pursuant to Section 2.11, or (ii) successfully Divested to a Third Party [***].

[***]

[***]

[***]

[***]

[***]
Furthermore, Phase A may lead to the identification of [***] listed in Exhibit 4; these antibodies will likewise qualify for the payment of the three million US dollars according to this Section 10.1(d) if Biontech demonstrates using flow cytometry that [***].

For the avoidance of doubt, the payment under this Section 10.1(d) shall not be considered a milestone payment, and shall not become due nor payable upon the achievement of any other milestones set forth in this Agreement, but only upon occurrence of the events set forth in this Section 10.1(d).

10.2 **Upfront payment by [***] for use of [***] Antibodies.** [***] shall pay to [***] the following non-refundable payments on an LCA Product-by-LCA Product or [***] Unilateral Product-by-[***] Unilateral Product basis incorporating a [***] Antibody in a [***]

Tumor Targeting Product Concept:

(a) [***] within [***] following the date on which the Joint Research Committee for the first time and in accordance with Section 2.10 (as documented by the minutes of the Joint Research Committee) selects a Preferred Clinical Candidate which incorporates a Genmab Antibody in a Tumor Targeting Product Concept, and such Preferred Clinical Candidate is either (i) advanced to an LCA Product pursuant to Section 2.10 or (ii) a [***] Unilateral Product pursuant to Section 2.11;

(b) [***] within [***] following the date on which (i) the Joint Steering Committee determines that there is Freedom-to-Operate for the [***] Antibody included in the LCA Product in accordance with the criteria set forth and agreed by the Joint IP Committee or (ii) [***] determines that there is Freedom-to-Operate for the [***] Antibody included in the Unilateral Product in accordance with the criteria set forth and agreed by the Joint IP Committee. The criteria shall stipulate that there shall be Freedom-to-Operate provided no claims of a patent issued in the [***] or [***] expiring after [***] disclose the [***] Antibody included in the LCA Product or Unilateral Product or use thereof for the treatment of cancer indications contemplated for the LCA Product or Unilateral Product as reflected in the applicable development plan, and provided no [***] application, [***] application or [***] application exists expiring after [***] with narrow and concrete claims covering the Genmab Antibody included in the LCA Product or Unilateral Product or use thereof for the treatment of cancer indications contemplated for the LCA Product or Unilateral Product as reflected in the applicable development plan. Further criteria may be defined and agreed by the Joint IP Committee in connection with the Selection of a Clinical Candidate. The Freedom-to-Operate determination shall be made prior to the filing of an IND. Should [***] determine that there is not Freedom-to-Operate with respect to a Unilateral Product it shall provide [***] with written evidence in support of that finding under a joint defense agreement to be entered into by the Parties.

For the avoidance of doubt, the payment under Section 10.2(a) and Section 10.2(b) shall not be considered a milestone payment, and shall not become due or payable upon the achievement of any other milestones set forth in this Agreement, but only upon occurrence of the events set forth in this Section 10.2(a) or Section 10.2(b).
10.3 **Payment by [***] for use of [***] Antibodies**. [***] shall pay to [***] the following non-refundable payment on an LCA Product-by-LCA Product or Unilateral Product-by-Unilateral Product basis incorporating a [***] Antibody in a [***] Tumor Targeting Product Concept:

[***] within [***] following the dosing of the [***] patient in the first Phase I Clinical Trial (or the first part of a Phase I/II Clinical Trial) for the [***] Indication.

This payment shall be in addition to any payments due for a Unilateral Product as set forth in Exhibit 1. For the avoidance of doubt, the payment under this Section 10.3 shall not be considered a milestone payment, and shall not become due or payable upon the achievement of any other milestones set forth in this Agreement, but only upon occurrence of the events set forth in this Section 10.3.

10.4 **Upfront payment by [***] for use of [***] Antibodies in a Tumor Targeting Product Concept**. [***] shall pay to [***] the following non-refundable payments on an LCA Product-by-LCA Product or Unilateral Product-by-Unilateral Product basis incorporating an [***] Antibody in a Tumor Targeting Product Concept:

(a) [***] within [***] following the date on which the Joint Research Committee for the first time and in accordance with Section 2.10 (as documented by the minutes of the Joint Research Committee) selects a Preferred Clinical Candidate which incorporates an [***] Antibody in an [***] Tumor Targeting Product Concept; and such Preferred Clinical Candidate is either (i) advanced to an LCA Product pursuant to Section 2.10 or (ii) a [***] Unilateral Product pursuant to Section 2.11;

(b) [***] within [***] following the date on which (i) the Joint Steering Committee determines that there is Freedom-to-Operate for the [***] Antibody included in the LCA Product in accordance with the criteria set forth and agreed by the Joint IP Committee or (ii) [***] determines that there is Freedom-to-Operate for the [***] Antibody included in the Unilateral Product in accordance with the criteria set forth and agreed by the Joint IP Committee. The criteria shall stipulate that there shall be Freedom-to-Operate provided no claims of a patent issued in the [***] or [***] expiring after [***] disclose the [***] Antibody included in the LCA Product or Unilateral Product or use thereof for the treatment of cancer indications contemplated for the LCA Product or Unilateral Product as reflected in the applicable development plan, and provided no [***] application, [***] application or [***] application exists expiring after [***] with narrow and concrete claims covering the [***] Antibody included in the LCA Product or Unilateral Product or use thereof for the treatment of cancer indications contemplated for the LCA Product or Unilateral Product as reflected in the applicable development plan. Further criteria may be defined and agreed by the Joint IP Committee in connection with the Selection of a Clinical Candidate. The Freedom-to-Operate determination shall be made prior to the filing of an IND. Should [***] determine that there is not Freedom-to-Operate with respect to a Unilateral Product it shall provide [***] with written evidence in support of that finding under a joint defense agreement to be entered into by the Parties.
For the avoidance of doubt, the payment under Section 10.4(a) and Section 10.4(b) shall not be considered a milestone payment, and shall not become due or payable upon the achievement of any other milestones set forth in this Agreement, but only upon occurrence of the events set forth in Section 10.4(a) or Section 10.4(b).

10.5 **Payment by [***]:** for use of [***] Antibodies in [***] Tumor Targeting Product Concept. [***] shall pay to [***] the following non-refundable payment on an LCA Product-by-LCA Product or [***] Unilateral Product-by-[***] Unilateral Product basis incorporating an [***] Antibody in an [***] Tumor Targeting Product Concept:

[***] within [***] weeks following the dosing of the [***] patient in the first Phase I Clinical Trial (or the first part of a Phase I/II Clinical Trial) for the [***] Indication.

This payment shall be in addition to any payments due for a Unilateral Product as set forth in Exhibit 1. For the avoidance of doubt, the payment under this Section 10.5 shall not be considered a milestone payment, and shall not become due or payable upon the achievement of any other milestones set forth in this Agreement, but only upon occurrence of the events set forth in this Section 10.5.

For the avoidance of doubt, if an LCA Product becomes a Unilateral Product, the payments already made for the LCA Product pursuant to Sections 10.2 – 10.5 (inclusive), as applicable, shall be deemed paid for the Unilateral Product and shall not become payable again.

10.6 **Future LCA Products or Unilateral Products using additional proprietary antibodies.** In case the Parties decide, by prior written agreement, to include further Antibodies proprietary to either of the Parties into the scope of their activities under this Agreement, the principles outlined in Sections 10.2 – 10.5 (inclusive) and Section 12.1(i) shall apply with respect to such proprietary Antibodies, and this Agreement shall be amended accordingly to reflect this. For the avoidance of doubt, if any such further proprietary Antibodies are to be used in combination with an [***] Antibody, a [***] Antibody or a [***] Antibody, payments are still due for the use of an [***] Antibody, a [***] Antibody or a [***] Antibody in accordance with the principles outlined in Sections 10.2 – 10.5 (inclusive), in addition to any other payments in respect of the use of such further proprietary Antibodies that may be agreed in writing by the Parties.

10.7 **FTE Rate.** The Parties agree that the mutual annual rate per FTE of either Party who performs research, Development, consultation or support work under any Research or Development Plan is as follows:

(a) Up until and including 18th May 2018: [***].
(b) From and including 19th May 2018 up until and including 30 March 2019: [***].
(c) From and including 1 April 2019 up until and including 30 March 2020: [***].
(d) From and including 1 April 2020 up until and including 30 June 2020: [***].
(e) From and including 1 July 2020 up until and including 31 December 2020: [***].
(f) From and including 1 January 2021 up until and including 31 December 2021: [***].
(g) From and including 1 January 2022 and onwards: [***] which shall be adjusted on an annual basis in accordance with the following sentence: [***].

10.8 Allocation of Research and Development Costs, Commercialization Costs and Profits. Unless otherwise set forth in this Agreement,
(a) all Research and Development Costs incurred by the Parties in the performance of the Research Plan or any Development Plan as well as all Commercialization costs according to the provisions of the respective Commercialization Plan and/or Commercialization Agreement, and any other costs expressly stated to be “Shared Costs” hereunder (collectively the Shared Costs) shall be shared equally by the Parties; and
(b) all Profits received by the Parties from the Commercialization of LCA Products and all [***] shall be accounted for by the Parties and shared equally between them (Shared Profits).

For avoidance of doubt, Biontech shall bear all and any costs, fees, royalties and other payments payable to [***] relating to Biontech’s [***], identified in [***], as well as [***] and such payments shall not be included in the calculation of Shared Costs.

10.9 Control of Shared Costs by Joint Research Committee or Joint Steering Committee or Joint Commercialization Committee. The Parties are obligated to each fund fifty percent (50 %) of costs associated with the research and Development of an LCA Product and equally share all Commercialization costs. For clarity, this includes without limitation FTE Costs as well as external Third Party costs. The Parties shall only be entitled to incur Shared Costs which are either (i) set forth in the annual Research Plan, the applicable annual Development Plan or the applicable Commercialization Plan, (ii) have been agreed and approved in advance by the competent Joint Research Committee, Joint Steering Committee or Joint Commercialization Committee, as applicable, or (iii) are in accordance with the Travel Policy. The Joint Steering Committee, if such committee is in place, if not the Joint Research Committee, shall review on a quarterly basis the Research and Development Costs and the Commercialization costs, as applicable, against the Budget for such expenses in the applicable calendar year (as further described in Section 10.11 below). If in the course of such quarterly review, the Joint Steering Committee determines that the actual
amounts incurred for Research and Development Costs or Commercialization costs are likely to be higher than budgeted or if either Party reasonably considers that it is likely to exceed the Budget of any Shared Costs set forth in the applicable Research Plan or Development Plan or Commercialization Plan or approved by the competent Joint Research Committee or Joint Steering Committee, or Joint Commercialization Committee, as applicable, it shall promptly notify the competent Joint Research Committee or Joint Steering Committee, or Joint Commercialization Committee thereof and shall provide such Joint Research Committee or Joint Steering Committee, or Joint Commercialization Committee with details of the additional Shared Costs that it expects to incur and the reason for such increase. The Joint Research Committee or Joint Steering Committee, or Joint Commercialization Committee shall then review the information submitted and may, if appropriate, amend the Research Plan or the affected Development Plan or the affected Commercialization Plan for the LCA Product to permit such overrun or to reduce such activities such that no overrun is expected. If the Joint Research Committee or Joint Steering Committee, or Joint Commercialization Committee does not approve the additional Shared Costs, the requesting Party shall have the right to incur such costs on its own behalf (so that the relevant costs items will not form part of the Shared Costs mechanism agreed hereunder). However, if the budget overrun is due to a delay or an advance in timing as to the planned activities, which activities are in accordance with the Research Plan or the relevant Development Plan or the relevant Commercialization Plan, then such excess Research and Development Costs or Commercialization costs shall be shared equally by the Parties regardless of which Party has incurred such costs. For the avoidance of doubt, if a Joint Steering Committee or Joint Commercialization Committee is in place for a certain LCA Product, then all matters set forth in this Section 10.9 pertaining to such LCA Product, shall be handled by the Joint Steering Committee or Joint Commercialization Committee, as applicable, whereas all other matters, if any, pertaining to Shared Costs on Clinical Candidates shall be handled by the Joint Research Committee.

10.10 Financial Representatives. Each Party will appoint a representative with expertise in the areas of accounting, cost allocation, budgeting and financial reporting (a “Financial Representative”). Such Financial Representatives shall work under the direction of the Joint Steering Committee and provide services to and consult with the Joint Steering Committee, Joint Development Team and Joint Commercialization Committee, in order to address the financial, budgetary and accounting issues which arise in connection with the performance of the Development Plan or the Commercialization. Each Financial Representative may be replaced at any time by the represented Party by providing written notice thereof to the other Party. The Financial Representatives will meet at least once each Calendar Quarter or as they or the Joint Steering Committee may agree. The Financial Representatives shall agree upon the timing and agenda for all regular meetings. The location of regularly scheduled meetings shall alternate between the offices of the Parties, unless otherwise agreed. Meetings may be held telephonically or by video conference. One of the Financial Representatives shall record (or cause

53 of 122
to have recorded the minutes of the meeting in writing. Such minutes shall be circulated to the other Financial Representative promptly following the meeting for review, comment and approval. If no comments are received within [*]** days of the minutes’ receipt by the other Financial Representative, unless otherwise agreed, they shall be deemed to be approved by such Financial Representative. Following their approval, the minutes shall be provided to each Party’s Alliance Manager. Each Party shall bear its own costs associated with its Financial Representative, including without limitation travel time and travel expenses, preparation for meetings, reading and approving meetings minutes.

10.11 **Shared Costs Reports.** Following the Effective Date, within [*]** after the end of every Calendar Quarter, each Party’s Financial Representative shall deliver to the Financial Representative of the other Party a written report showing in reasonable detail the Shared Costs that it has incurred during such Calendar Quarter (a **Shared Costs Report**). The Shared Costs Reports will be in such form as the Financial Representatives may reasonably agree from time to time. Unless otherwise agreed between the Parties, within [*]** after the end of each Calendar Quarter, the Financial Representatives (or the Party as agreed by the Financial Representatives) shall provide to each Party one consolidated financial report for the Shared Costs consistent with Collaboration Accounting Principles. The Joint Research Committee or Joint Steering Committee or Joint Commercialization Committee, as applicable shall review such reports and shall determine any compensation amount due by one Party to the other for such Calendar Quarter to reflect the equal sharing agreed under Section 10.8(a). The Party entitled to any such compensation amount shall invoice the relevant compensation amount (plus any value-added tax, if applicable) to the other Party. Invoices are payable within [*]** after receipt.

10.12 **Profit Reports and Payment.** The Parties shall mutually agree, through the Joint Steering Committee, a mechanism or structure under which they will share equally (50:50) in all Shared Profits created by each LCA Product. In reaching this agreement the Parties shall also define and mutually agree, through the Joint Steering Committee, the appropriate arrangements for making reports and payments between the Parties.

10.13 **Financial Provisions Relating to Proprietary Combination Products.**

(a) **Costs.** Except as otherwise specified in this Agreement, all costs related to any Proprietary Combination Study shall be borne by the Developing Party.

(b) **Profit Sharing.** Subject to Section 10.13(e), all Profits received by either Party from the commercialization of [*]** which are generated through the commercial exploitation of the Proprietary Combination Product [*]** shall be shared equally between the Parties in accordance with Sections 10.8(b) and 10.12 of this Agreement. [*]** For clarity, for the purposes of this Agreement, [*]** shall be considered an integral component of the “Profit” as defined in Section 1.137. For further clarity, there shall be no obligation to share the profit generated from the sale of [*]** or, if applicable, [*]** or [*]**.
10.14 Audit

(a) Shared Costs and Shared Profits Records. For so long as any research, development and/or Commercialization activities are conducted hereunder in respect of an LCA Product or any research, development and/or commercialization activities are conducted hereunder in respect of [***] included in a Proprietary Combination Product, and for a period of [***] years thereafter, each Party shall keep and maintain, and shall require its Affiliates to keep and maintain, accurate and complete cost records of activities performed by each such Party (including without limitation Shared Costs and Shared Profits incurred and FTEs utilized) in connection with its research, development and commercialization activities hereunder. Not more than once per calendar year, each Party shall have the right to engage an independent certified public accounting firm of internationally recognized standing and reasonably acceptable to the other Party, which shall have the right to examine in confidence the relevant books, records or other relevant reports, of such other Party and its respective Affiliates as may be reasonably necessary to determine and/or verify the accuracy of the reports submitted to the Joint Steering Committee, Joint Research Committee or Joint Commercialization Committee, as applicable, in connection with the performance of a Party’s Development obligations and Commercialization rights hereunder in respect of an LCA Product (or its development obligations and commercialization rights hereunder in respect of [***] included in a Proprietary Combination Product).

(b) Audit Procedure. Such examination shall be conducted, and each Party shall make its records available, during normal business hours, after at least [***] days prior written notice shall have been provided by the other Party, as applicable, and shall take place at the facility(ies) where such records are maintained. Each such examination shall be limited to pertinent books, records and reports for any year ending not more than [***] months prior to the date of request; provided, that, no Party shall be permitted to audit the same period of time more than once. Before permitting such independent accounting firm to have access to such books and records, the non-requesting Party may require such independent accounting firm and its personnel involved in such audit to sign a confidentiality agreement (in form and substance reasonably acceptable to such Party) as to any Confidential Information which is to be provided to such accounting firm or to which such accounting firm will have access while conducting the audit under this paragraph. The accounting firm shall provide both Biontech and Genmab with a written report stating whether the reports submitted by Biontech or Genmab, as applicable, are correct or incorrect and the specific details concerning any discrepancies. Such accounting firm may not reveal to the other Party any information learned in the course of such audit other than the amount of any such discrepancies. Each Party agrees that all such information shall be Confidential Information of the other Party and further agrees to hold in strict confidence all information disclosed to it in accordance with Section 14.
[c] Cost of Audit. The Party initiating such audit shall bear the full cost of such audit unless such audit discloses that the actual expenses incurred in the conduct of the other Party's obligations under the Research Plan or a Development Plan, as applicable, are lower than that reported by such Party by [***] percent (\([***]\)% or more, in which case the other Party shall reimburse the initiating Party for all costs incurred by the initiating Party in connection with such audit. Furthermore, the amount in excess of the actual expenses shall be deducted from the Shared Costs reported by that Party and reconciled between the Parties.

10.15 Dispute Resolution. In the event of any dispute between the Parties in relation to the determination of Shared Costs or Shared Profits or either Party's share in the Shared Costs or Shared Profits, the Parties shall appoint an international firm of independent certified accountants as Third Party expert to decide on the issue in dispute (and if the Parties cannot agree on such expert, each party shall appoint one accounting firm and both accounting firms so appointed shall select the relevant expert). The Third Party expert shall be entitled to request any information and documents from either Party that it deems relevant for rendering its decision, and each Party shall be obliged to provide such information and documents as quickly as possible. Prior to rendering a decision, the Third Party expert shall provide each Party with reasonable opportunity to comment on its preliminary findings. The decision of the Third Party expert shall be final and binding upon both Parties. The costs of the Third Party expert shall be borne by the losing Party or, if the Third Party expert does not fully confirm either Party’s view, shall be shared on a pro rata basis between the Parties as reasonably determined by the Third Party expert.

10.16 General Payment Terms. All payments under this Agreement shall be made in United States Dollars (except for any FTE costs to be reimbursed by one Party to the other hereunder under the cost sharing mechanism which shall be made in Euro) and are exclusive of applicable statutory value-added tax (VAT), if any, which shall be listed separately on each invoice. Each payment under this Agreement shall be made by electronic transfer in immediately available funds via bank wire transfer to such bank account as the respective Party shall designate in writing to the other Party. All amounts accruing in a currency other than United States Dollars or Euro, as applicable, will be expressed in such currency and converted to United States Dollars or Euro, as applicable, using the exchange rate mechanism generally applied by such Party, provided that such mechanism is in compliance with IFRS. The conversion calculations will be provided in any statement reporting converted amounts. Any undisputed payments or portions thereof due hereunder which are not paid on the date such payments are due under this Agreement will bear interest at a rate equal to five (5) percent points above the then-applicable base lending rate of the European Central Bank, or (b) the maximum rate permitted by law, calculated on the number of days such payment is delinquent, compounded monthly using a three hundred sixty five (365) day year.

56 of 122
10.17 Tax Matters.

(a) Except as otherwise provided below, all amounts due from any paying Party to any receiving Party under this Agreement are gross amounts. The paying Party shall be entitled to deduct the amount of any withholding taxes payable or required to be withheld under Applicable Laws by it, its Affiliates, licensees, or Sublicensees (as applicable) to the extent such paying Party, its Affiliates, licensees, or Sublicensees (as applicable) actually pay such withheld amounts to the appropriate governmental authority on behalf of the receiving Party. Any such tax required to be withheld shall be an expense of and borne by the receiving Party. The paying Party and the receiving Party shall cooperate with respect to all documentation required by any governmental authority or reasonably requested by either Party to secure a reduction in the rate of applicable withholding taxes. The paying Party shall use Commercially Reasonable Efforts to optimize any such taxes, levies or charges required to be withheld on behalf of the receiving Party. The paying Party promptly shall deliver to the receiving Party proof of payment of all such taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect thereto, and shall cooperate with the receiving Party in seeking any related tax credits that may be available to the receiving Party with respect thereto. If the paying Party had a duty to withhold taxes in connection with any payment it made to the receiving Party but the paying Party failed to withhold, and such taxes were assessed against and paid by the paying Party, then the receiving Party shall (at the paying Party’s request and upon receipt of proof of the paying Party’s payment of such taxes) reimburse the paying Party an amount equivalent to such taxes paid by the paying Party. For the avoidance of doubt, the receiving Party shall further indemnify and hold harmless the paying Party from and against any related interest or penalties that are imposed by any governmental authority against the paying Party as withholding agent (in addition to any such taxes).

(b) Value-added Tax and Other Indirect Taxes: As and when required by Applicable Law, any non-recoverable value-added tax or similar indirect taxes, goods and services tax or similar sales taxes or duties actually incurred by either Party and imposed by any governmental agency as a result of this Agreement (Applicable Taxes) will be invoiced at current statutory rates and paid from one Party to the other Party in addition to contracted direct costs and pass through costs. If any Applicable Taxes become due, these shall be listed separately on each invoice. For clarity, if and to the extent any Applicable Taxes are to be paid by either Party these Applicable Taxes can only be oncharged if these are not recoverable by either Party, all attention and diligence and in accordance with any and all Applicable Laws applied. If the Applicable Taxes are or subsequently become recoverable, pass through cost shall be invoiced net of any Applicable Taxes.
Except as otherwise set forth in this Section 10.17, 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.

11. GOVERNANCE

11.1 Alliance Managers. Each Party shall appoint one or more persons to coordinate its part of the activities under this Agreement (each an Alliance Manager). The Alliance Managers shall be the primary contacts between the Parties with respect to all activities performed under this Agreement and shall be responsible for overseeing the operation of the collaboration of the Parties under this Agreement and the organization of the committees. The Alliance Managers will meet in person or per telephone or video conference as necessary to fully comply with their responsibilities. They shall report to the Joint Research Committees and Joint Steering Committee. Either Party may change its Alliance Manager(s) upon written notice to the other Party. The Alliance Managers shall have no authority to amend or modify the terms and conditions of the Research Plan, any Development Plan or of this Agreement.

11.2 Joint Research Committee. Within [***] days following the Effective Date, the Parties shall establish a joint research committee (Joint Research Committee). The Joint Research Committee shall have a total of up to [***] members. Up to [***] members of the Joint Research Committee shall be appointed by Genmab, and up to [***] members of the Joint Research Committee shall be appointed by Biontech. Each Joint Research Committee member shall have sufficient authority to ensure acceptance and execution of Joint Research Committee decisions within its organization. Each Party may appoint substitutes or alternates for its Joint Research Committee members at any time by written notice the other Party. The Parties may mutually agree to change the size of the Joint Research Committee at any time. The Joint Research Committee shall be established for the entire term of Phase A as set forth in Section 2.5. For the avoidance of doubt, the Joint Research Committee may co-exist with one or several Joint Steering Committees.

(a) Responsibilities of the Joint Research Committee. The Joint Research Committee shall be responsible for directing, coordinating and supervising the research and development activities of the Parties during Phase A. In particular, the Joint Research Committee shall:

(i) review and endorse the initial Research Plan proposed by the Parties according to Section 2.2;

(ii) review and update the Research Plan on an ongoing basis as set forth in Section 2.2;

(iii) receive regular reports from each Party’s research (or project) team on, and monitor, the conduct, progress and results of each Party’s activities under the Research Plan,
(iv) agree in advance, review and approve the Shared Costs that the Parties are entitled to incur in Phase A,
(v) review and approve the appointment of certain subcontractors pursuant to Section 2.4(b), and
(vi) resolve any issues referred to it by the Parties in accordance with Section 20.10.

(b) Meetings of the Joint Research Committee. Meetings of the Joint Research Committee shall be scheduled from time to time by mutual agreement of the Parties or upon request of one Party, but in no event less than once every [***] months. The meetings may be held in person, per telephone or video conference. The Parties shall alternate chairing meetings of the Joint Research Committee, with Genmab chairing the first such meeting after the Effective Date. The Alliance Manager of the Party hosting any Joint Research Committee meeting shall attend the meeting and record the minutes of the meeting in writing. Such minutes shall be circulated to the other Party’s Alliance Manager no later than [***] following the meeting for review, comment and approval of the other Party. If no comments are received within [***] of the receipt of the minutes by a Party, unless otherwise agreed, they shall be deemed to be approved by such Party. Furthermore, if the Parties are unable to reach agreement on the minutes within [***] of the applicable meeting, the sections of the minutes that have been mutually agreed between the Parties by that date shall be deemed approved and, in addition, each Party shall record in the same document its own version of those sections of the minutes on which the Parties were not able to agree.

(c) Decisions of the Joint Research Committee. A quorum of at least [***] Joint Research Committee members appointed by each Party shall be present at or shall otherwise participate in each Joint Research Committee meeting. Each Party has one vote in the decisions of the Joint Research Committee. Decisions of the Joint Research Committee shall be unanimous. If the members of the Joint Research Committee cannot agree on a particular issue, the issue shall be escalated pursuant to Section 20.10. The Joint Research Committee shall have no authority to amend or modify the terms and conditions of this Agreement.

11.3 Joint Steering Committee. No later than [***] days after the first initiation of Phase B for a LCA Product (as documented in the minutes of the Joint Research Committee), the Parties shall establish a joint steering committee (Joint Steering Committee) having a total of up to [***] members which shall have sufficient authority to ensure acceptance and execution of Joint Steering Committee decisions within its organization. Up to [***] members of the Joint Steering Committee shall be appointed by Genmab, and up to [***] members of the Joint Steering Committee shall be appointed by Biontech. Each Party may appoint substitutes or alternates for its Joint Steering Committee members at any time by written notice the other Party. The Parties may mutually agree to change the size of the Joint Steering Committee at any time.
(a) **Responsibilities of Joint Steering Committee.** The Joint Steering Committee shall be responsible for directing, coordinating and supervising the research and Development activities of the Parties during Phase B. In particular, the Joint Steering Committee shall:

(i) review and endorse the initial Development Plan and Budget proposed by the Parties according to Section 3.2;

(ii) review and approve the Development Plan as proposed by the Joint Development Team, including without limitation the Budget for an LCA Product and approve necessary updates or amendments thereto;

(iii) receive regular reports from the Joint Development Team on, and monitor, the conduct, progress and results of each Party’s activities under the applicable Development Plan;

(iv) review and approve strategies proposed by the Joint Development Team for the Development of each LCA Product, including but not limited to clinical trial designs for each LCA Product and prioritization of clinical trials (including but not limited to Phase III Clinical Trials) and Indications for each LCA Product, and ensuring that such strategies are compatible;

(v) agree in advance, review on a quarterly basis and approve the Shared Costs that the Parties are entitled to incur in Phase B;

(vi) review and approve regulatory strategies proposed by the Joint Development Team for each LCA Product in the Territory, including without limitation ensuring that such strategies are compatible;

(vii) upon a Party’s request, review and determine whether Biontech should be the Lead Regulatory Party for a particular LCA Product in a particular country or region pursuant to Section 7.1;

(viii) review and discuss the goals and strategy for the manufacture of each LCA Product;

(ix) oversee the Parties’ negotiations of a potential Commercialization Agreement pursuant to Section 6.5;

(x) review and endorse the goals and strategy for the Commercialization of each LCA Product as submitted by the Joint Commercialization Committee and approve an initial Commercialization Plan for each LCA Product as well as oversee the Joint Commercialization Committee, once such is established;

(xi) review and endorse the overall IP strategy as prepared by the Joint IP Committee;

(xii) oversee and handle a Joint Divestment Process as set forth in Section 18.9;

60 of 122
(xiii) oversee the Joint Development Team and all subcommittees, if any, as deemed necessary;
(xiv) serve as the forum for the settlement of disputes or disagreements that are unresolved by the Joint Development Team or any of the subcommittees;
(xv) approve the Collaboration Accounting Policies and the Travel Policy;
(xvi) review and approve the appointment of certain subcontractors pursuant to Section 3.3(b);
(xvii) review and approve any proposed amendments to the list of Permitted Subcontractors set out in Exhibit 10 promptly following the Execution Date (and, in any event, no later than [***], unless otherwise agreed by the Parties) and thereafter on an annual basis (commencing on the first anniversary of [***]);
(xviii) review the recommendations proposed by the Joint Development Team and decide upon the nomination of any strategic partner(s) (including but not limited to for the development of companion diagnostics), if any, including without limitation approving any related budget;
(xix) review and determine whether to take a Proprietary Combination License pursuant to Section 13.7 and Exhibit 12; and
(xx) resolve any issues referred to it by the Parties in accordance with Section 20.10.

(b) For the avoidance of doubt, the Joint Steering Committee shall have no responsibilities with respect to any Unilateral Products.

(c) Subcommittees. The Joint Steering Committee may, from time to time, establish subcommittees not already dealt with pursuant to this Agreement. The Joint Steering Committee may determine the charter, composition and other provisions relating to any such subcommittee in its discretion.

(d) Role after End of Development and Commercialization. The Joint Steering Committee shall continue to operate after the end of all Development and/or Commercialization activities for the last LCA Product to the extent needed in order to deal with any subsequent issues. Following the end of such Development and/or Commercialization, the Joint Steering Committee shall however not be obliged to convene at the times stipulated above, but merely when needed in order to address the issues at hand. Once the Joint Steering Committee unanimously decides that its responsibilities have been exhausted, then the Joint Steering Committee may dissolve itself.

(e) Meetings and Decisions of the Joint Steering Committee. Sections 11.2(b) and 11.2(c) shall apply mutatis mutandis to the Joint Steering Committee, save that the decision of the Joint Steering Committee shall be final in respect of Section 11.3(a)(vii) such that if the members of the Joint Steering Committee cannot agree on this issue, then Biontech shall not act as the Lead Regulatory Party for such LCA Product in such country or region and the issue shall not be escalated pursuant to Section 20.10.
11.4 **Approval of Proprietary Combination Studies by Joint Steering Committee.** Notwithstanding the above in Section 11.3 of this Agreement, to the extent the Joint Steering Committee has to approve any Proprietary Combination Study (or any changes to any such Proprietary Combination Study) in accordance with Sections 4.2 or 4.3 of this Agreement, the following terms and conditions shall apply:

(a) **No Unreasonable Rejection.** The Joint Steering Committee shall not unreasonably withhold or delay any approval of any proposed Proprietary Combination Study.

(b) **[***] Proprietary Combination Studies.** With respect to [***] Proprietary Combination Studies, the Joint Steering Committee may only withhold its consent if (i) [***] (ii) [***] (iii) [***]. The Parties agree that the Developing Party cannot file any IP or, subject to the terms of Section 14.7, publish any research results using Collaboration Product data from a [***] Proprietary Combination Study without the Non-Developing Party’s (prior written) consent in accordance with Section 12.11.

(c) **[***] Proprietary Combination Studies.** With respect to [***] Proprietary Combination Studies, the Joint Steering Committee may only withhold its approval if:

(i) [***]

(ii) [***]

(iii) [***]

(iv) [***]

(d) **Exclusivity.** [***]

11.5 **Joint Development Team.** Concurrently with the establishment of the Joint Steering Committee or as soon as possible after an additional LCA Product has been selected by the Joint Research Committee pursuant to Section 2.10, as applicable, on an LCA Product-by-LCA Product basis, the Parties shall – on a project level – establish a joint development team, to monitor, coordinate and implement all activities for the Development of an LCA Product according to the Development Plan (the **Joint Development Team**). The Joint Development Team shall consist of such number of representatives of each Party as are reasonably necessary to accomplish the goals of the Joint Development Team hereunder. Either Party may replace any or all of its representatives at any time upon notice to the other Party.
(x) Joint Development Team Responsibilities. The Joint Development Team shall perform the following functions:

(i) develop an overarching strategy and detailed plans for the Development of each LCA Product (including without limitation the Development Plan for each LCA Product) for review and approval by the Joint Steering Committee;

(ii) oversee and manage the work under, monitor the progress of, and implement the Development Plan, including without limitation compliance with budget and timelines;

(iii) formulate any changes to the Development Plan (including without limitation allocation of Development activities between the Parties) and the Budget for review and approval by the Joint Steering Committee, such Development Plan to always take into account the potential Development scenarios in the subsequent [***] year Development of the LCA Product, even to the extent such Development scenarios extend beyond completion of the first Phase I/II Clinical Trial;

(iv) make recommendations for further Development of the LCA Product, including without limitation Development of the LCA Product for Indications that are not contemplated in the then current Development Plan;

(v) review and agree on forecasts of supply requirements of the LCA Product for Development (including [***]) and review and monitor the manufacturing and supply of LCA Product for Development;

(vi) align on clinical trial designs to ensure support of the overall Development strategy;

(vii) discuss and exchange information regarding the conduct of ongoing clinical trials;

(viii) exchange information regarding the LCA Product and facilitate cooperation and coordination between the Parties relating to the Development of the LCA Product as they exercise their respective rights and meet their respective obligations under the Development Plan and this Agreement;

(ix) evaluate possibilities and recommend to the Joint Steering Committee any potential strategic partner(s) (including but not limited to for the development of companion diagnostics), if any, for approval by the Joint Steering Committee;

(x) provide status updates to the Joint Steering Committee regarding Development activities; and

(xi) perform such other functions as appropriate to further the purposes of this Agreement as determined by the Parties.
Meetings of the Joint Development Team. Section 11.2(b) shall apply mutatis mutandis to the Joint Development Team, except for the fact that it is not the Alliance Manager, but instead the applicable Development Team Leader who shall record the minutes of the meeting in writing.

Decisions of the Joint Development Team. A quorum of at least [***] Joint Development Team members appointed by each Party shall be present at or shall otherwise participate in each Joint Development Team meeting. Each Party has one vote in the decisions of the Joint Development Team. Decisions of the Joint Development Team shall be unanimous. In the event that the Joint Development Team members do not reach consensus with respect to a matter that is within the purview of the Joint Development Team within [***] calendar days after they have met and attempted to reach such consensus, such matter shall be presented to the Joint Steering Committee for resolution.

Duration of Joint Development Team Operations. The Joint Development Team will be in existence commencing upon its date of formation and shall continue in existence until the date on which both Parties have completed all their activities as provided for in the Development Plan, unless the Joint Steering Committee agrees to extend the term further.

Development Team Leaders. One representative from each Party shall be designated to act as the primary Joint Development Team contact for that Party (Development Team Leader). The Development Team Leaders shall be responsible for alignment of the development strategy of the LCA Product between the different business functions of the Parties and for ensuring the day-to-day implementation of the Development Plan, including without limitation coordinating the activities of the different business functions of the Parties and the Joint Development Team members. The Development Team Leaders are allowed to delegate their responsibilities as set forth in this Section 11.5(e) within his/her organization as appropriate.

Joint Commercialization Committee. The Parties shall in due time during Phase B but no later than thirty (30) days after the Joint Steering Committee’s approval of the first Phase III Clinical Trial intended to support a Marketing Approval of a LCA Product, establish a joint commercialization committee (Joint Commercialization Committee). The Joint Commercialization Committee shall have a total of up to [***] members. Up to [***] members of a Joint Commercialization Committee shall be appointed by Genmab, and up to [***] members of a Joint Commercialization Committee shall be appointed by Biontech. Each Joint Commercialization Committee member shall have sufficient authority to ensure acceptance and execution of Joint Commercialization Committee decisions within its organization. Each Party may appoint substitutes or alternates for its Joint Commercialization Committee members at any time by written notice the other Party. The Parties may mutually agree to change the size of the Joint Commercialization Committee at any time.

Responsibilities of Joint Commercialization Committee. The Joint Commercialization Committee shall be responsible for coordinating and supervising the Commercialization of the respective LCA Product. In particular, the Joint Commercialization Committee shall:
(i) review and approve the Commercialization Plan and authorize necessary updates or amendments thereto,
(ii) agree on the overall strategy for Commercialization of an LCA Product, including but not limited to pricing and marketing matters,
(iii) review and approve the Shared Profits reported by the Parties in accordance with Section 10.12, and
(iv) resolve any issues referred to it by the Parties in accordance with Section 20.10.

(b) For the avoidance of doubt, the Joint Commercialization Committee shall have no responsibilities with respect to any Unilateral Products.

(c) Meetings and Decisions of the Joint Commercialization Committee. Sections 11.2(b) and 11.2(c)) shall apply mutatis mutandis to the Joint Commercialization Committee.

11.7 Travel Costs. The costs and expenses of a Party’s research and development representatives (including without limitation members of the Joint Research Committee, Joint Steering Committee, Joint Development Team members, scientists and Joint Commercialization Committee, patent attorneys, project managers) which are incurred in connection with the conduct of any meetings under this Section 11 (Meetings) shall be deemed to be Shared Costs to be shared equally by the Parties. Shared Costs shall be those related to any Meetings taking place as of the 1st of July 2019 and until expiry or termination of this Agreement. For clarity, costs and expenses relating to a Party’s other representatives attending any Meetings (including without limitation representatives from supporting functions such as alliance management, business development, finance and legal) shall not be deemed to be Shared Costs and shall not be shared by the Parties.

12. INTELLECTUAL PROPERTY

12.1 Ownership

(a) Ownership of [***] Technology and [***] Technology. Genmab shall during the Term of this Agreement and thereafter exclusively own all right, title and interest in and to the [***] Technology. Biontech shall during the Term of this Agreement and thereafter exclusively own all right, title and interest in and to the [***] Technology.

(b) Disclosure of Program Inventions. Each Party shall promptly disclose to the other Party the making, conception or reduction to practice of any inventions directly arising out of activities conducted during this Agreement or the Prior Agreement (Program Inventions).
(c) Ownership of [***] Inventions. All right, title and interest in all [***] Inventions shall be owned as follows:

(i) Except as set forth in subsections (ii) and (iii) below, Genmab and Biontech shall jointly own all [***] Inventions (Collaboration IP).

(ii) Genmab shall own all [***] Inventions that are not [***] and that are invented solely or jointly by employees, agents or consultants of Genmab and/or Biontech and solely relate to the [***] Technology ([***] Improvement Technology). To the extent that any such [***] Inventions relating solely to the [***] Technology shall have been invented by Biontech and/or are owned by Biontech, Biontech hereby assigns all of its right, title and interest therein to Genmab.

(iii) Biontech shall own all [***] Inventions that are not [***] and that are invented solely or jointly by employees, agents or consultants of Genmab and/or Biontech and solely relate to the [***] Technology ([***] Improvement Technology). To the extent that any [***] Inventions relating solely to the [***] Technology shall have been invented by Genmab and/or are owned by Genmab, Genmab hereby assigns all of its right, title and interest therein to Biontech.

(iv) For clarity, as between the Parties, any [***] Inventions relating to, or covering:

1. the combined use of [***] included in any [***] shall constitute Collaboration IP and be jointly owned by the Parties.
2. solely the [***] included in any [***] shall constitute Collaboration IP and be jointly owned by the Parties.
3. solely any [***] included in any [***] shall be owned in accordance with, and pursuant to, the terms of [***] or [***] (respectively).
4. [***] shall be owned by the Party that [***].

(d) Terms of Joint Ownership. The Collaboration IP (including, without limitation, any Joint Patents) shall, subject to the terms and conditions of this Agreement, be equally and undividedly owned by the Parties, but a Party cannot exploit or transfer its interest in the Collaboration IP, unless specifically permitted under this Agreement or otherwise agreed in writing by the Parties. A Party shall not assign, mortgage, sell or otherwise transfer or dispose of any of its right, title or interest in any Collaboration IP without the other Party’s prior written consent (not to be unreasonably withheld or delayed), save that such consent shall not be required in respect of any transfer to: (a) an Affiliate of the Party; (b) a Third Party successor or purchaser of all or substantially all of its business or assets to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other similar transaction; or (c) a Third Party that acquires, by purchase or license, rights to further develop or commercialize the related LCA Product following a Joint
Divestment Process in accordance with Section 18.9; provided that, in each case, any such transfer shall be made subject to the license granted to the other Party pursuant to this Agreement, [***] and [***], as applicable, and that the Affiliate or Third Party, as applicable, agrees, by written notice to the other Party, to be bound by the terms of such license and all other terms of this Agreement, [***] and [***] to the extent that such terms are applicable to the assigned Collaboration IP. Nothing herein shall entitle a Party to take any other action under the Collaboration IP other than as explicitly permitted in this Agreement, and the other Party is entitled to oppose any exploitation of the Collaboration IP falling outside the scope of this Agreement. Notwithstanding the above, the Parties may have an interest in using the Collaboration IP outside the scope of this Agreement, [***] or [***] for its own products (provided that such use is not in connection with (i) a Proprietary Combination Product which shall be subject to the terms of this Agreement or (ii) any equivalent proprietary combination product under equivalent terms in [***] or [***] which shall be subject to the terms of [***] or [***], as applicable) such as for Biontech RNA vaccines, TLR ligands and/or cell therapies. Upon the request of a Party, the Joint Steering Committee or Joint Research Committee, if no Joint Steering Committee is in place, shall arrange for negotiations in good faith of a license under the Collaboration IP for such purposes on reasonable terms.

(e) **Filing of Patent Applications.** Unless otherwise agreed by the Joint IP Committee, any patent application disclosing, covering or claiming Collaboration IP shall not be filed until the respective Clinical Candidate has been selected as an LCA Product.

(f) **Special rules for New Patents.** Notwithstanding sub-section (e) above, the Parties acknowledge that a patent, claiming certain Collaboration IP generated by the Parties under the Prior Collaboration Agreement relating to [***] antibodies which are based on Genmab’s [***] and which comprises one or more of Biontech’s [***], has been filed on [***] under application no. [***] (such [***] and any Patent Right subsequently granted thereunder including but not limited to [***] shall be referred to as the *New Patents*). The filing of such application had been agreed pursuant to the Parties’ first side letter dated 8 January 2016. The Parties acknowledge and agree that the New Patents shall be subject to and governed by the terms set out in Exhibit 7.

(g) **Assignment of Collaboration IP for Unilateral Products.** In case of an opt-out pursuant to Section 18, the Continuing Party shall be the sole owner of Collaboration IP solely related to the relevant Unilateral Product [***] and the Opt-Out Party shall arrange for a transfer of (i) all of its rights, title and interest in any such Collaboration IP (the *Assigned Patents*), and (ii) all substantive documentation pertaining to such Collaboration IP, if any. Following assignment of the applicable Collaboration IP to the Continuing Party, the Continuing Party shall be solely responsible for the further preparation, filing, prosecution and maintenance of any Assigned Patents at its own cost. The Opt-Out Party may negotiate in good faith licenses to use the Assigned Patents outside the scope of this Agreement, [***] and [***].
the last two sentences of Section 12.1(d) shall apply mutatis mutandis. Should the Continuing Party decide not to file or to abandon or let lapse an Assigned Patent regarding such Unilateral Product, the Continuing Party shall notify the Opt-Out Party of such decision at least [***] calendar days prior to the expiration of any deadline relating to such activities, and the Opt-Out Party shall thereafter have the right, but not the obligation, to assume responsibility for filing, prosecuting and maintaining such Assigned Patent, at its sole expense. If the Opt-Out Party does elect to pursue such filing, prosecution or maintenance of such Assigned Patent, then it shall notify the Continuing Party of such election, and the Continuing Party shall execute such documents of transfer or assignment and perform such acts as may be reasonably necessary to preserve and transfer to the Opt-Out Party free of charge all its right, title and interest in and to any such Assigned Patent in such country. Notwithstanding the foregoing, Biontech agrees and acknowledges that Genmab shall remain the sole owner of the DuoBody Platform and the [***] Technology, and that any activities by Biontech as the Continuing Party under this Section 12.1(g) that pertain to the DuoBody Platform and/or the [***] Technology shall at all times be subject to Genmab's prior consultation, review and written consent, such consent not to be unreasonably withheld.

(h) **Ceased Products.** With regards to Collaboration IP on Ceased Product(s), provided that such Ceased Product(s) have not previously been an LCA Product for which Development has been ceased, the Parties agree to [***].

(i) **Certain Joint Patent Filings.** The Parties agree, with respect to any joint patent filings on any LCA Product or Unilateral Product incorporating a [***] Antibody in an [***] Tumor Targeting Product Concept or an [***] Antibody in an [***] Tumor Targeting Product Concept, that the Parties shall only be allowed to specifically disclose the Preferred Clinical Candidate and one (1) Back-up Candidate, if applicable, in such joint patent filings, unless the Parties mutually agree that further Bispecific Antibodies may be included.

(j) **[***] Patent Application.** The Parties agree that all Patent Rights arising from patent application [***] filed on [***] and the subsequent application [***] filed on [***] in accordance with the terms of the letter agreement to the Prior Collaboration Agreement dated [***] shall be solely owned by Biontech.

12.2 **Ownership in Relation to Proprietary Combination Products.**

(a) **Proprietary Combination Product IP.** All right, title and interest in any inventions relating to, or covering, [***] (the "Proprietary Combination Product IP") shall be [***]. For clarity, any such Proprietary Combination Product IP shall not constitute [***] Inventions under this Agreement. For further clarity, nothing in this Section 12.2(a) shall require either Party to assign or transfer to the other Party any Patent Right that constitutes Collaboration IP which: (a) has been filed prior to the commencement of a [***] Proprietary Combination Study under Section 4.2; and (b) claims or covers the Proprietary Combination Product of such [***] Proprietary Combination Study.
12.3 **License to Genmab.** For the purpose of the Research under Phase A and subsequently on an LCA Product-by-LCA Product basis and subject to the terms of this Agreement, Biontech hereby grants Genmab a worldwide, co-exclusive (with Biontech and subject to the exclusivities set forth in Section 9), royalty-free license, including without limitation the right to sublicense in the course of subcontracting (as approved by the Joint Steering Committee), under the Biontech Technology during the Term to (a) perform its obligations hereunder with respect to activities under the Research Plan and each LCA Product in accordance with the relevant Development Plan, (b) to conclude Partnership Agreements in accordance with the procedures set forth in Section 6.7 and (c) to research, develop, have developed, make, have made, import, use, offer for sale, have sold and sell such LCA Product within the Field in the Territory. The license for an LCA Product shall continue, on a country-by-country basis, for so long as there are Development or Commercialization activities contemplated. For the avoidance of doubt, the term “co-exclusive” shall mean that only Genmab and Biontech shall have the right to use the Biontech Technology to the exclusion of all others (save for permitted sublicensees). Biontech hereby acknowledges and agrees that Genmab has granted a sublicense for the purpose of performing the Research Plan and further Development activities to its wholly owned subsidiary, Genmab B.V., the Netherlands, Genmab US, Inc., USA, and Genmab K.K., Japan. For clarity, similar licenses permitting the use of intellectual property rights relating to [***] or [***] included in a Joint Combination Product under this Agreement are granted in [***] or [***] (respectively).

12.4 **License to Biontech.** For the purpose of the Research under Phase A and subsequently on a LCA Product-by-LCA Product basis and subject to the terms of this Agreement, Genmab hereby grants Biontech a worldwide, co-exclusive (with Genmab and subject to the exclusivities set forth in Section 9), royalty-free license, including without limitation the right to sublicense in the course of subcontracting (as approved by the Joint Steering Committee), under the Genmab Technology during the Term to (a) perform its obligations hereunder with respect to activities under the Research Plan and each LCA Product in accordance with the relevant Development Plan, (b) to conclude Partnership Agreements in accordance with the procedures set forth in
Section 6.7 and (c) to research, develop, have developed, make, have made, import, use, offer for sale, have sold and sell such LCA Product within the Field in the Territory. The license for a LCA Product shall continue, on a country-by-country basis, for so long as there are development or commercialization activities contemplated. For the avoidance of doubt, the term "co-exclusive" shall mean that only Genmab and Biontech shall have the right to use the Genmab Technology to the exclusion of all others (save for permitted sublicensees). The licenses granted to Biontech under this Section 12.4 with regards to the DuoBody Platform are only granted for the [***]. Use of other [***] under the DuoBody Platform can only take place upon Genmab’s prior written consent. The license granted under the [***] Technology is to [***]. For clarity, similar licenses permitting the use of intellectual property relating to [***] or [***] included in a Joint Combination Product under this Agreement are granted in [***] or [***] (respectively).

12.5 Licenses Relating to Proprietary Combination Products.

(a) Licenses to Developing Party. The Non-Developing Party hereby grants to the Developing Party under [***]:

(i) a non-exclusive, worldwide, royalty-free, fully paid-up, non-transferable license to the extent necessary or useful for the Developing Party to perform any Proprietary Combination Study approved by the Joint Steering Committee; and

(ii) a co-exclusive, worldwide, perpetual, royalty-free, fully paid-up, sublicensable, transferable license to develop, have developed, make, have made, import, use, offer for sale, have sold and sell any Proprietary Combination Product that is the subject of a [***] Proprietary Combination Study approved by the Joint Steering Committee pursuant to Section 4.3.

For clarity, the licenses granted under sub-sections (i) and (ii) above do not include any license to any Patent Rights or know-how owned or controlled by the Non-Developing Party in relation to [***], and the license to manufacture granted under sub-section (ii) above shall not include any right to [***]. For clarity, similar licences permitting the use of intellectual property rights relating to [***] or [***] included in a Proprietary Combination Product under this Agreement are granted in [***] or [***] (respectively).

(b) Licenses to Non-Developing Party. The Developing Party hereby grants to the Non-Developing Party under [***]:

(i) a non-exclusive, worldwide, perpetual, royalty-free, fully paid-up, sublicensable and non-transferable license to allow the Non-Developing Party to (x) [***] and (y) [***], in each case within the scope of the collaboration under, and subject to the terms and conditions of, this Agreement or [***] or [***]; and
subject to the terms and conditions of this Agreement, including existing exclusivity obligations set out in Section 9 of this Agreement, a non-exclusive, worldwide, perpetual, royalty-free, fully paid up, sublicensable and non-transferable unblocking license to research, develop, have developed, make, have made, import, use, offer for sale, have sold and sell its own Proprietary Combination Products.

12.6 **No Further Rights.** This Agreement shall not be construed to convey any right or license (a) to Biontech to use and/or exploit the Genmab Technology or (b) to Genmab to use and/or exploit the Biontech Technology, in each case for (a) and (b) except as specifically stipulated in this Agreement.

12.7 **Joint IP Committee.**

(a) Within [***] days of the Effective Date, the Parties shall establish a joint IP committee (the **Joint IP Committee**). The Joint IP Committee shall have a total of [***] members. [***] members of the Joint IP Committee shall be appointed by Genmab, and [***] members of the Joint IP Committee shall be appointed by Biontech. Each Joint IP Committee member shall have sufficient authority to ensure acceptance and execution of Joint IP Committee decisions within its organization. Each Party may appoint substitutes or alternates for its Joint IP Committee members at any time by written notice to the other Party. The Parties may mutually agree to change the size of the Joint IP Committee at any time.

(b) The Joint IP Committee shall convene with no less than [***] weeks’ notice unless shorter notice is required under the circumstances, for example in order to allow the Lead IP Party necessary time to comply with applicable timelines stipulated by any applicable authority. The Joint IP Committee shall hold meetings at least [***] per Calendar Quarter during the Term, or as otherwise agreed in writing between the Parties. Unless otherwise agreed in writing, such meetings shall alternate between a location selected by Genmab and a location selected by Biontech or take place via telephone or video conference or such other means as may be agreed in writing between the Parties. The meetings shall be prepared and convened by the chair of the Joint IP Committee. The chair shall alternate between representatives of each Party, starting with a Genmab representative as the chair. Within [***] weeks of every meeting, the chair shall prepare and send minutes of the meeting to the other members of the Joint IP Committee. The minutes shall be considered as approved by the members of the Joint IP Committee, unless the chair has received objections and/or comments to the minutes within [***] weeks after the minutes have been sent to the members of the Joint IP Committee. With respect to the decisions of the Joint IP Committee and costs, Sections 11.2(c) and 11.7 shall apply mutatis mutandis.
The Joint IP Committee shall prepare an overall IP strategy for all Collaboration IP to be endorsed by the Joint Steering Committee. In particular, the Joint IP Committee shall discuss and decide on all material issues pertaining to the governance of the Collaboration IP, including, but not limited to, the filing, prosecution, maintenance, defense and/or enforcement of the Collaboration IP, and shall agree on the IP Budget related thereto in accordance with the procedures set forth in Section 12.8(d). In addition, the Joint IP Committee shall also oversee all matters relating to any Proprietary Combination Product IP as further specified in Sections 12.2, 12.5, 12.11 and 12.12(e).

The decisions of the Joint IP Committee shall be binding on the Parties to the extent they pertain to the overall IP strategy and the governance of the Collaboration IP. In all other respects, the Joint IP Committee may make recommendations which shall not be binding on the Parties, but the Parties shall take due account of these recommendations when performing their rights and obligations set forth in this Agreement.

12.8 Lead IP Party

(a) Designation of Lead IP Party. The Parties agree that it is appropriate to designate one of the Parties to be responsible for (i) implementing the decisions of the Joint IP Committee, (ii) taking emergency measures in order to prosecute, maintain and defend the Collaboration IP, provided that such measures are of a preliminary nature where possible and shall be reviewed and approved by the Joint IP Committee without undue delay, and (iii) to act as the common representative towards the applicable authorities (such Party to be referred to as the Lead IP Party). The Joint IP Committee shall appoint a Lead IP Party for each Program Invention which is part of the Collaboration IP, taking into consideration the capabilities of each Party’s IP department and each Party’s specific expertise with respect to the relevant Program Invention.

(b) Power of Attorney. The Lead IP Party is hereby granted by the other Party (the Non-Lead Party) a power of attorney to conduct all such acts which rest with the Lead IP Party as specified in this Section 12.8. The Lead IP Party is only authorized to act within the parameters of the overall IP strategy as adopted by the Joint IP Committee and all other decisions of the Joint IP Committee pertaining to the governance of the Collaboration IP. Unless otherwise agreed in writing, the Lead IP Party shall be appointed for the entire Term of this Agreement with respect to the relevant Program Invention.

(c) Responsibilities of the Lead IP Party. The Lead IP Party shall – within the scope of its appointment by the Joint IP Committee – be responsible for the preparation, filing, prosecution and/or maintenance of Joint Patents and, if applicable, any other Collaboration IP in accordance with the decisions of the Joint IP Committee and subject always to Section 12.30(d). In particular, the Lead IP Party shall, in each case in accordance with the decisions of the Joint IP Committee:
(i) prepare and file patent applications, including without limitation divisional applications, continuation applications, continuation-in-part applications, and requests for continued examination, relating to the Collaboration IP, including without limitation any Joint Patents, with applicable intellectual property office(s) or authority(ies);

(ii) maintain Joint Patents and/or, if applicable, any other Collaboration IP, including without limitation taking such steps as may be reasonably necessary to ensure possible patent term extensions, renewals or supplementary protection certificates in respect of Joint Patents;

(iii) prosecute Joint Patents and/or, if applicable, any other Collaboration IP with national and/or regional intellectual property offices, including without limitation appeal to the courts, and prosecution hereof;

(iv) coordinate the payment of maintenance fees and other official fees or costs with national and/or regional intellectual property offices in respect of Joint Patents and/or, if applicable, any other Collaboration IP, and ensure that all maintenance fees are paid promptly when due, unless otherwise agreed in writing between the Parties; and

(v) provide the Non-Lead Party with all material information, and copies of material correspondence to and from patent/intellectual property offices and external patent attorneys and agents, pertaining to the filing, prosecution and maintenance of the Joint Patents and/or, if applicable, any other Collaboration IP, for review and approval. For any new patent application to be filed relating to the Collaboration IP, a draft shall be provided to the other Party for review as soon as possible before the filing date.

(d) IP Budget. The Lead IP Party shall prepare (and continuously update as appropriate) a budget for implementation of the overall IP strategy and the governance of the Collaboration IP (hereinafter, the IP Budget) to be included in the Budget that is to be reviewed and approved by the Joint Steering Committee in accordance with Section 11.3(a).

(e) Cooperation; Disputes. The Parties agree to act in good faith toward each other and to cooperate fully with each other in relation to the filing, prosecution and maintenance of the Joint Patents and/or, if applicable, any other Collaboration IP taking into consideration that both Parties have ownership interests in such intellectual property rights. The Parties further agree to coordinate, in good faith, the filing and prosecution of the Joint Patents with either Party’s filing and prosecution of Patent Rights covering the BioNTech Technology or the Genmab Technology, as applicable, while taking into consideration the individual and joint interests of both Parties. In case of a dispute, the matter shall be referred to the Joint IP Committee, which in turn shall refer any unresolved matter to the Joint Steering Committee. In case actions need to be taken during such dispute period to prevent Joint Patents from being abandoned, the Lead IP Party shall have final decision-making authority taking into due account the dispute and making efforts to maintain the status quo to the extent possible.
The Non-Lead Party shall, as reasonably requested by the Lead IP Party, assist the Lead IP Party and the Lead IP Party’s external patent counsel (if applicable) in the preparation, filing, prosecution and/or maintenance of Joint Patents and/or, if applicable, any other Collaboration IP, and the Parties shall cooperate with one another jointly to maintain the Joint Patents and/or, if applicable, any other Collaboration IP in force. The Parties shall perform such acts, execute such further instruments, documents or certificates, and provide such cooperation and assistance as may be reasonably requested by the other Party in order to give effect to the terms of this Section 12.8. Such assistance shall be deemed Shared Costs for the purposes of this Agreement.

12.9 Inventor Compensation. Each Party shall be responsible for payment of any consideration which it is required to pay to its employees or independent consultants or subcontractors as compensation for the assignment of rights to any Program Invention according to the legal provisions applicable in the relevant country and/or a contractual obligation.

12.10 Patent Prosecution, Maintenance and Defense

(a) Notification. Each Party shall promptly inform the other Party in writing of any allegation(s) or claim(s) from, or proceeding(s) initiated by, a Third Party which challenges the validity or enforceability of, or the Parties’ entitlement to, any Genmab Technology, Biontech Technology or any Collaboration IP, which comes to its attention, to the extent relevant to an LCA Product or, if applicable, a Unilateral Product for which such other Party is responsible, including without limitation (if applicable) pre-grant opposition, post-grant opposition, re-examination, interference or revocation proceedings (whether before any applicable intellectual property office or the courts), and shall provide the other Party with any available evidence thereof.

(b) Biontech Patents. Biontech shall be solely responsible for and shall solely control the preparation, filing, prosecution, grant, extension, maintenance and defense of all Biontech Patents excluding Biontech’s share in Joint Patents. Biontech shall, at its sole expense, prepare, file, prosecute and maintain such Biontech Patents in good faith consistent with its customary patent policy and its reasonable business judgment, and shall consider in good faith the interests of Genmab in so doing.

(c) Genmab Patents. Genmab shall be solely responsible for and shall solely control the preparation, filing, prosecution, grant, extension, maintenance and defense of all Genmab Patents excluding Genmab’s share in Joint Patents. Genmab shall, at its sole expense, prepare, file, prosecute and maintain such Genmab Patents in good faith consistent with its customary patent policy and its reasonable business judgment, and shall consider in good faith the interests of Biontech in so doing.
(d) **Collaboration IP.** The Parties shall be jointly responsible and shall jointly control the preparation, filing, prosecution, grant, extension, maintenance and defense of all Joint Patents and/or, if applicable, any other Collaboration IP, through the Joint IP Committee and the Lead IP Party, in accordance with the provisions of Section 12.7 and Section 12.8. Unless otherwise agreed upon in writing between the Parties, any application for a Joint Patent and/or, if applicable, any other Collaboration IP shall be filed under the name of both Parties.

(e) [***] and [***]. For clarity, any intellectual property rights in respect of [***] or [***] (including, without limitation, pursuant to Sections 12.1(c)(v)(3) and 12.2(d)) shall be prepared, filed, prosecuted, granted, extended, maintained and defended in accordance with, and pursuant to, the terms of [***] or [***] (respectively).

(f) **Counterclalm.** Notwithstanding Sections 12.10(a)-(d), if any court proceedings are brought against one Party or both Parties or their Affiliates alleging that any Biontech Patent, Genmab Patent or Joint Patent is invalid or unenforceable, or should be revoked or otherwise challenging a Party’s entitlement to such Patent Right (including, without limitation, any counter-claim by a Third Party pursuant to an enforcement action described in Section 12.12), then the terms of Section 12.12 shall apply mutatis mutandis with respect to any such defense litigation.

(g) **Cooperation.** If any claim by a Third Party relates to more than one category of relevant Patent Rights (i.e., each category being Biontech Patents, Genmab Patents and Joint Patents and Patent Rights in respect of [***] or [***]), such that the Parties would be required to defend more than one category of relevant Patent Rights at the same time, then the Parties shall cooperate in good faith with each other in connection with such defense.

(h) **Common Interest Disclosures.** With regard to any information or opinions disclosed pursuant to this Agreement by one Party to the other regarding intellectual property and/or technology owned by Third Parties, Biontech or Genmab (or their respective Affiliates), Biontech and Genmab agree that they have a common legal interest in coordinating prosecution of their respective patent applications, as set forth in this Section 12, and in determining whether, and to what extent, Third Party intellectual property rights may affect the conduct of the development, manufacturing, marketing and/or sale of LCA Products and Unilateral Products, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to the development, manufacturing, marketing and/or sale of LCA Products and Unilateral Products. Accordingly, Biontech and Genmab agree that all such information and opinions obtained by Biontech and Genmab from each other will be used solely for purposes of the Parties’ common legal interests with respect to the conduct of this Agreement. All information and opinions will be treated as protected by the attorney-client privilege, the work product privilege, and any other privilege or immunity that may otherwise be applicable. By sharing any such information and opinions, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and opinions. Neither Party shall have the authority to waive any privilege or immunity on behalf of the other Party without such other Party’s prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against any other Party.

75 of 122
12.11 Prosecution, Maintenance and Defense of Proprietary Combination Product IP.

(a) Timing. Unless otherwise agreed in good faith in writing between the Parties, [***] shall not be allowed to file any application for any Patent Right for any Proprietary Combination Product IP prior to [***] or [***].

(b) Process. [***] shall be responsible for and shall control the preparation, filing, prosecution, grant, extension, maintenance and defense of all Patent Rights relating to any Proprietary Combination Product IP [***], subject to the following requirements:

(i) At least [***] days prior to filing any application for any Patent Right relating to any Proprietary Combination Product IP, [***] shall provide the Joint IP Committee with the draft application as well as any material information in connection with such draft application (including copies of material correspondence from any external patent attorneys and agents pertaining thereto) for any such Patent Rights.

(ii) The Joint IP Committee shall review the draft application with respect to any potential overlap with the [***]. Any concerns in relation to the draft application shall be discussed in good faith in the Joint IP Committee and [***] shall consider in good faith any comment made by [***]. In the event of a dispute between the Parties regarding the content of the draft application, [***].

(iii) Following any filing of any application for any such Patent Right, [***] shall keep the Joint IP Committee informed of all material developments in relation to such Patent Right, including any potential material correspondence from patent/intellectual property offices or any opposition or other claims of any Third Party with respect of such Patent Right. Any material submission by [***] to any patent/intellectual property offices in relation to such Patent Right shall be discussed in good faith in Joint IP Committee and [***] shall consider in good faith any comment made by [***]. In the event of a dispute between the Parties regarding any such material submission, [***].

(iv) The Parties shall seek to act timely in their review and approval of any matter under this Section 12.11(b) in order to allow [***] to comply with relevant filing deadlines or similar time limitations.

76 of 122
(c) [***] [***] shall [***] responsible for and shall [***] control the preparation, filing, prosecution, grant, extension, maintenance and defense of all Patent Rights relating to any [***].

(d) **Common Interest Disclosure.** Section 12.10(h) of this Agreement shall apply mutatis mutandis to any information or opinions disclosed relating to the [***] of any Proprietary Combination Product by one Party to the other regarding intellectual property and/or technology owned by [***] Biontech or Genmab (or their respective Affiliates).

**12.12 Enforcement of Patents**

(a) **Notification.** Each Party shall promptly inform the other Party in writing of any actual or suspected infringement of, or unauthorized use by a Third Party of any Genmab Technology, Biontech Technology, Collaboration IP or any Proprietary Combination Product IP, which comes to its attention, to the extent relevant to an LCA Product or, if applicable, a Unilateral Product or Proprietary Combination Product for which such other Party is responsible, and shall provide the other Party with any available evidence thereof.

(b) **Enforcement of [***] Patents.** [***] shall have the sole right, at its sole expense, but not the obligation, to determine the appropriate course of action to enforce the [***] Patents (other than its interests in the Joint Patents) or otherwise abate the infringement thereof, to take (or refrain from taking) appropriate action to enforce such [***] Patents, to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to the [***] Patents so long as this does not adversely affect [***]'s rights under this Agreement. [***] shall fully cooperate with [***] at [***]'s sole expense, in any action to enforce the [***] Patents. All monies recovered upon the final judgment or settlement of any such suit to enforce such [***] Patents shall be retained by [***].

(c) **Enforcement of [***] Patents.** [***] shall have the sole right, at its sole expense, to determine the appropriate course of action to enforce [***] Patents (other than its interest in Joint Patents), or otherwise to abate the infringement thereof, to take (or refrain from taking) appropriate action to enforce such [***] Patents, to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to such [***] Patents. All monies recovered upon the final judgment or settlement of any such suit to enforce such [***] Patents shall be retained by [***]. [***] shall fully cooperate with [***] at [***]'s sole expense, in any action to enforce the [***] Patents.
(d) Enforcement of Joint Patents.

(i) The Joint IP Committee shall determine any required or desirable action to abate any infringement of any Collaboration IP by any Third Party, which action shall then be implemented by the Lead IP Party (Infringement Proceedings). The Parties shall share equally (50:50) all costs, both internally and externally, associated with any such joint Infringement Proceedings, unless otherwise agreed in writing. The Parties shall also share equally (50:50) any damages, royalties, settlement fees or other consideration resulting from any such joint Infringement Proceedings, unless otherwise agreed in writing.

(ii) The Lead IP Party shall keep the Non-Lead Party informed of the status of any such joint Infringement Proceedings and, upon request, shall (to the extent permitted under Applicable Law) provide the Non-Lead Party, at no cost to the Non-Lead Party, with copies of all documents filed in, and all material written communications between the parties relating to, such Infringement Proceedings. The Non-Lead Party shall, at the Lead IP Party’s request, give the Lead Party all reasonable assistance in any such joint Infringement Proceedings.

(iii) No settlement shall be entered into by the Lead IP Party without the prior written consent of the Non-Lead Party (such consent not to be unreasonably withheld or delayed).

(e) Enforcement of Patents relating to Proprietary Combination Product IP or [***]. [***]

(f) [***] and [***]. For clarity, any intellectual property rights in respect of [***] or [***] (including, without limitation, pursuant to Sections 12.1(c)(iv)(3) and 12.2(d)) shall be enforced against Third Parties in accordance with, and pursuant to, the terms of [***] and [***] (respectively).

12.13 Assignment of Inventor’s Rights. To the extent the assignment of inventions is not effected by statutory law (e.g. the German Employees’ Inventions Act), each Party will maintain valid and enforceable written agreements with all persons acting for or on behalf of such Party or its Affiliates which require such person to assign to such Party their entire right, title and interest in and to all Collaboration IP, Biontech Improvement Technology (in case of Genmab), Genmab Improvement Technology (in case of Biontech) and any other intellectual property rights that are to be owned by the other Party (alone or jointly by the Parties) pursuant to the terms of this Agreement. To the extent necessary to obtain full ownership rights in such inventions for such Party (e.g. under the German Employees’ Inventions Act), each Party shall “claim” from all persons acting for or on behalf of such Party or its Affiliates the ownership of any such invention constituting any Collaboration IP, [***] Improvement Technology (in case of [***]), [***] Improvement Technology (in case of [***]) and any other intellectual property rights that are to be owned by the other Party (alone or jointly by the Parties) pursuant to the terms of this Agreement which are conceived, reduced to practice, developed or created in the conduct of the activities performed under this Agreement.
12.14 **LCA Product Trademarks.** With regards to LCA Product(s), the Parties shall propose and through the Joint Steering Committee select the trademark, trade dress, logos and slogans under which each LCA Product shall be exclusively marketed (each a *LCA Product Trademark*). Such activities shall be handled by the Lead Commercialization Party of such Region. The Lead Commercialization Party shall register the LCA Product Trademark and shall take all such actions as are required to continue and maintain in full force and effect the trademarks and the registrations thereof as well as enforce such trademarks and registrations. The Parties shall jointly own the trademarks which are specifically directed to LCA Products and the other Party shall execute all documents and take all actions as are reasonably requested by the Lead Commercialization Party to effectuate such joint ownership in such trademarks unless such joint ownership would not be practicable in any such jurisdiction, in which case the Lead Commercialization Party for the applicable Region shall have sole ownership. LCA Product Trademarks shall be used only pursuant to the terms of this Agreement and the Commercialization Agreement to identify, and in connection with the marketing of, LCA Products. For clarity, the selection, registration and ownership of any trademark for [***] or [***] included in any Joint Combination Product or Proprietary Combination Product shall be subject to the terms of [***] or [***] (respectively).

13. **INFRINGEMENT ACTIONS BROUGHT BY THIRD PARTIES**

13.1 **Third Party License.** Each Party shall promptly inform the other Party in writing if it deems that a license of any intellectual property rights owned or controlled by a Third Party is needed to Develop or Commercialize an LCA Product or develop or commercialize a Unilateral Product for which the other Party is responsible (*FTO Notification*). If the FTO Notification concerns an LCA Product, the Parties will discuss and agree any required or advisable measures in respect of the same in the Joint IP Committee and/or the relevant Joint Steering Committee. If the FTO Notification concerns a Unilateral Product, the respective Continuing Party shall be solely responsible for the course of action but will closely consult with the respective Opt-Out Party.

13.2 **LCA Product.** Each Party will promptly notify the other Party in writing if it becomes aware of any Third Party alleging that the performance of this Agreement infringes Third Party intellectual property rights (*Infringement Attack*). If an Infringement Attack is directed against the manufacture, use, handling, storage, Development, Commercialization or other disposition of an LCA Product, the Parties shall consult in good faith through the Joint IP Committee with a view to agreeing any required or desirable defense to any such Infringement Attack. Each Party shall have the right to defend itself against the Infringement Attack in accordance with the decisions and instructions of the Joint IP Committee. Notwithstanding the preceding
sentence, Genmab shall be solely responsible for the defense against Infringement Attacks solely directed against the use of [***] Technology [***] and Biontech shall be solely responsible for the defense against Infringement Attacks solely directed against the use of [***] Technology [***], in both scenarios in close consultation with the other Party. In no event may a Party settle or otherwise consent to an adverse judgment that diminishes the rights or interests of the other Party without the express written consent of the other Party not to be unreasonably withheld.

13.3 Defense Costs. If the alleged infringement relates to an LCA Product and is not subject to indemnification pursuant to Section 17.2(a), all reasonable costs associated with the defense of the Infringement Attack and approved by the Joint IP Committee, including without limitation any payment due to such Third Party as damages or in settlement allocated to sales of the LCA Product, will be shared equally (50:50) between the Parties as part of the Shared Costs. For the avoidance of doubt, each Party will individually bear the risks and costs of infringing Third Party patents in the course of its activities which are outside of the scope of this Agreement.

13.4 Genmab Unilateral Product. To the extent an Infringement Attack is directed against the manufacture, use, handling, storage, development, commercialization or other disposition of a Genmab Unilateral Product, Genmab shall be solely responsible for the defense and all costs associated therewith, except that:

(a) this shall be carried out in close consultation with Biontech, unless instructed otherwise in writing by Biontech; and
(b) Biontech shall have the first right to control at its sole cost the defense against such Infringement Attack to the extent it is directed against the use of Biontech Technology, provided that Genmab shall be entitled to participate in such defense. If Biontech chooses not to defend against Infringement Attacks related to the Biontech Technology, then Genmab shall have the right to control such defense on its own.

13.5 Biontech Unilateral Product. To the extent an Infringement Attack is directed against the manufacture, use, handling, storage, development, commercialization or other disposition of a Biontech Unilateral Product, Biontech shall be solely responsible for the defense and all costs associated therewith, except that:

(a) this shall be carried out in close consultation with Genmab, unless instructed otherwise in writing by Genmab; and
(b) Genmab shall have the first right to control at its sole cost the defense against such Infringement Attack to the extent it is directed against the use of Genmab Technology, provided that Biontech shall be entitled to participate in such defense. If Genmab chooses not to defend against Infringement Attacks related to the Genmab Technology, then Biontech shall have the right to control such defense on its own.
13.6 [***] and [***]. To the extent an Infringement Attack is directed against the manufacture, use, handling, storage, development, commercialization or other disposition of [***] or [***] as part of a Joint Combination Product, the defense (and all associated costs) of such Infringement Attack shall be conducted in accordance with, and pursuant to the terms of, [***] and [***] (respectively).

13.7 **Third Party License Relating to a Proprietary Product Combination.** The Developing Party or the Non-Developing Party, as applicable, shall promptly notify the Joint IP Committee in writing if it deems that a license of any intellectual property rights owned or controlled by a Third Party may be needed to [***] or [***] a Proprietary Combination Product. If the notification does not relate in any way to [***] or [***] included in such Proprietary Combination Product, [***] shall [***] responsible for determining the appropriate course of action with respect to any such intellectual property rights owned or controlled by a Third Party, [***] will keep the Joint IP Committee informed of any such action. If the notification relates (also) to [***] or [***] included in such Proprietary Combination Product, the course of action taken with respect to such intellectual property rights owned or controlled by a Third Party (including, without limitation, taking a license under the same (“Proprietary Combination License”)) shall be determined by the Joint Steering Committee and the principles set forth in Exhibit 12 shall apply. Section 13.3 (Defense Costs) of this Agreement shall apply mutatis mutandis solely to the extent that an alleged infringement relates to the use of [***] in combination with [***] and such alleged infringement is not solely due to the use of [***].

13.8 **[***] Antibodies.** The Parties acknowledge that the use of any [***] Antibodies in an LCA Product or Unilateral Product shall be subject to the terms and conditions of the [***] Agreement, including without limitation the financial terms as outlined in Exhibit 6. The Parties shall share the payments pursuant to the [***] Agreement in case of an LCA Product. [***] shall be solely responsible for the payments pursuant to the [***] Agreement with respect to a [***] Unilateral Product, and [***] shall be solely responsible for the payments pursuant to the [***] Agreement with respect to a [***] Unilateral Product, and shall reimburse [***] for all payments due under the [***] Agreement for such [***] Unilateral Product. [***] hereby grants to [***] a sublicense under its rights under the [***] Agreement for the [***] Antibodies it being understood that Sections 12.4, 18.6(c) and 18.6(d) of this Agreement shall apply mutatis mutandis to this sublicense, except that the payment structure with respect to the [***] Agreement shall be as set forth in this Section 13.8.

13.9 **[***] Antibodies.** The Parties acknowledge that the use of any [***] Antibodies in an LCA Product or Unilateral Product shall be subject to the terms and conditions of the [***] Agreement. [***] is an [***] (as that term is defined in the [***] Agreement). [***] hereby grants to [***] a sublicense under its rights under the [***] Agreement for the [***] Antibodies it being understood that Sections 12.4, 18.6(c) and 18.6(d) of this Agreement shall apply mutatis mutandis to this sublicense.
13.10 **Antibodies.** Biontech declares that the use of any ***Antibodies in an LCA Product or Unilateral Product are not subject to any special terms or conditions of an underlying agreement.

14. CONFIDENTIALITY

14.1 **Confidentiality and Restricted Use.** Each Party (Receiving Party) shall protect the Confidential Information of the other Party (Disclosing Party) from unauthorized use or disclosure and use at least the same standard of care as it uses to protect its own Confidential Information and to make sure that its and its Affiliates’ employees, agents, consultant and clinical investigators only make use of the Disclosing Party’s Confidential Information for the purposes expressly authorized or contemplated by this Agreement. All Confidential Information disclosed by the Developing Party to the Non-Developing Party in connection with any Proprietary Combination Product or any Proprietary Combination Study ***shall constitute Confidential Information of ***and shall be treated as such by ***in accordance with this Section 14. For clarity, ***Technology and ***Technology (and records containing details of the same) shall be deemed to be the Confidential Information of the Party or Parties which owns such ***Technology or ***Technology, as applicable pursuant to the terms of this Agreement (e.g., jointly owned Collaboration IP and Joint Patents (and records containing details of the same) shall constitute Confidential Information of both Parties).

14.2 **Disclosure to Third Parties.** Neither Party shall, except with the express prior written consent of the Disclosing Party, disclose any Confidential Information of the Disclosing Party to any person or entity other than its or its Affiliates’ officers, directors, employees, agents, consultants, Sublicensees and Approved Subcontractors who need to know such information for the performance of this Agreement and who are bound by a written confidentiality agreement not less stringent than the terms of this Agreement or by professional rules of secrecy. Notwithstanding the foregoing, each Party may disclose the existence of, and terms and conditions of, this Agreement, without the consent of the other Party, to advisors, existing and potential investors, licensees, assignees and/or acquirers on a need to know basis under circumstances that reasonably ensure the confidentiality thereof.

14.3 **Permitted Disclosures.** The above confidentiality obligations shall not apply to information which, as can be established by the Receiving Party,

(a) was rightfully communicated to the Receiving Party or its Affiliates from a Third Party; or

(b) was already in the public domain or subsequently entered the public domain through no fault of the Receiving Party and its Affiliates; or

(c) was already known by the Receiving Party or its Affiliates prior to disclosure by the Disclosing Party or was developed independently by the Receiving Party or its Affiliates without reference to or reliance upon Confidential Information provided by the Disclosing Party; or

82 of 122
(d) is to be disclosed pursuant to any Applicable Law or legal, regulatory or stock exchange requirement, provided that the Receiving Party shall wherever possible provide prior written notice of such disclosure to the Disclosing Party and take reasonable and lawful actions to avoid or minimize the degree of disclosure. Notwithstanding the foregoing sentence, if such information is to be disclosed pursuant to any industry guidance to which a Party is subject, the Receiving Party shall not make such disclosure except with the express prior written consent of the Disclosing Party (such consent not to be unreasonably withheld, conditioned or delayed). The Parties agree that nothing in this Section 14.3(d) is intended to require a Party not to comply with any Applicable Law; or

(e) are required to be disclosed solely to the extent reasonably necessary in a patent application claiming Program Inventions made hereunder to be filed with the United States Patent and Trademark Office and/or any other intellectual property office, provided that the Party filing the patent shall provide at least thirty (30) days prior written notice of such disclosure to the other Party and take reasonable and lawful actions to avoid or minimize the degree of disclosure; or

(f) constitutes an Agreed TSA as further described in Section 3.11.

14.4 Press releases, references. Upon the Effective Date, Genmab will issue a company announcement and Biontech intends to issue an initial media release the wordings of such announcement and release have been approved by the Parties and are set forth in Exhibit 5. In addition, each Party shall be entitled to disclose the other Party’s name as collaboration partner under this Agreement to Third Parties and use the other Party’s name solely for such purposes. All other use of the other Party’s name in any advertising or promotional material, or any other publicity relating to this Agreement, shall require the other Party’s prior written consent. Except for the initial media release and company announcement permitted above, neither Biontech nor Genmab will, without the prior consent of the other, issue any press release or make any other public announcement or furnish any statement to any person or entity (other than to either Parties’ respective Affiliates and/or to either Party’s and/or an Affiliate’s shareholders to the extent required by Applicable Law) concerning the existence of this Agreement, its terms and the transactions contemplated hereby, except for disclosures expressly permitted hereunder.

14.5 Publication regarding LCA Products. The Parties shall only jointly make publications regarding any LCA Product(s), except as provided below in this Section 14.5. If a Party wishes to publish, present or announce results of LCA Product Developed hereunder either orally or in writing (a Publication) on its own, it shall provide the non-publishing Party with a draft copy of such Publication in advance. The non-publishing Party shall have [***] days from receipt of a proposed draft Publication to provide comments and/or proposed changes to the publishing Party. The publishing Party shall take into account the comments and/or proposed changes made by the non-publishing Party on any Publication and shall agree to designate employees or others acting on
behalf of the non-publishing Party as co-authors on any Publication describing results to which such persons have contributed in accordance with standards applicable to authorship of scientific publications. If the non-publishing Party reasonably determines that the Publication would entail the public disclosure of such non-publishing Party’s Confidential Information and/or of a patentable invention upon which a patent application should be filed prior to any such disclosure, submission of the concerned Publication to Third Parties shall be delayed for such period as may be reasonably necessary for deleting any such Confidential Information of the non-publishing Party (if the non-publishing Party has requested deletion thereof from the proposed Publication), and/or the drafting and filing of a patent application covering such invention, provided such additional period shall not exceed [***] days from the date the publishing Party first provided the proposed Publication to the non-publishing Party. For clarity, Section 14.3(d), but not this Section 14.5, is intended to apply to any announcements required by either Party under Applicable Law, including but not limited to notifications to the relevant stock exchanges.

14.6 **Publication regarding Unilateral Products.** A Continuing Party may on its own make a Publication on a Unilateral Product developed hereunder. If a Continuing Party wishes to make such a Publication, it shall provide the Opt-Out Party with a draft copy of such Publication in advance. The Opt-Out Party shall have [***] days from receipt of a proposed Publication to provide comments and/or proposed changes to the Continuing Party. To the extent such comments and/or proposed changes pertain to the Opt-Out Party’s technology, the Continuing Party shall take into account the comments and/or proposed changes made by the Opt-Out Party on any Publication. If the Opt-Out Party reasonably determines that the Publication would entail the public disclosure of such Opt-Out Party’s Confidential Information and/or of a patentable invention upon which a patent application should be filed prior to any such disclosure, submission of the concerned Publication to Third Parties shall be delayed for such period as may be reasonably necessary for deleting any such Confidential Information of the Opt-Out Party (if such Opt-Out Party has requested deletion thereof from the proposed Publication), and/or the drafting and filing of a patent application covering such invention, provided such additional period shall not exceed [***] days from the date the Continuing Party first provided the proposed Publication to the Opt-Out Party. For clarity, Section 14.3(d), but not this Section 14.6, is intended to apply to any announcements required by either Party under Applicable Law, including but not limited to notifications to the relevant stock exchanges.

14.7 **Publication regarding Proprietary Combination Products.** Prior to the initiation of any [***] Proprietary Combination Study in relation to any Proprietary Combination Product, neither Party shall publish any information in relation to the Proprietary Combination Product without the other Party’s prior written consent. After the initiation of a [***] Proprietary Combination Study, the Developing Party shall have the right to make publications regarding such Proprietary Combination Study, provided that the Developing Party complies with the provisions set out below in this Section 14.7. Prior
to any publication, the Developing Party shall provide to the Non-Developing Party the full details of the proposed publication in an electronic version (in a readable format) for review. The Non-Developing Party shall have [***] days from receipt of a proposed publication to provide comments and/or proposed changes to the Developing Party. The Developing Party shall take into account the comments and/or proposed changes made by the Non-Developing Party and shall agree to designate employees or others acting on behalf of the Non-Developing Party as co-authors on any publication describing results to which such persons have contributed in accordance with standards applicable to authorship of scientific publications. If the Non-Developing Party reasonably determines that the publication would entail the public disclosure of the Non-Developing Party’s Confidential Information [***] and/or of a patentable invention upon which a patent application should be filed prior to any such disclosure, submission of the concerned publication to Third Parties for publication shall be delayed for such period as may be reasonably necessary for deleting any such Confidential Information of the Non-Developing Party [***] and/or the drafting and filing of a patent application covering such invention, provided that such additional period shall not exceed [***] days from the date the Developing Party first provided the proposed publication to the Non-Developing Party. [***] For further clarity, nothing in this Section 14.7 shall limit the Developing Party’s right to disclose any Confidential Information of the Non-Developing Party or of both Parties in any announcements to the extent required by any Applicable Law or legal, regulatory or stock exchange requirement, provided that the Developing Party shall wherever possible provide prior written notice of such disclosure to the Non-Developing Party and take reasonable and lawful actions to avoid or minimize the degree of disclosure.

14.8 Prior Agreement. As of the Effective Date, the above confidentiality obligations shall supersede any oral or written confidentiality agreements concluded between the Parties prior to this Agreement. As far as under such prior confidentiality agreement or the Prior Agreement information has already been exchanged, the above provisions of this Section 14 shall apply also to such information.

14.9 [***] Agreement. With respect to the redacted copy of the [***] Agreement that has been provided to Biontech pursuant to side letter no. 4 dated 6 October 2020, the following shall apply:

(a) The disclosure of the redacted copy of the [***] Agreement shall be subject to Sections 14.1 through 14.3 above with the following modifications:

(b) Biontech shall keep the redacted copy of the [***] Agreement confidential for an indefinite period of time.

(c) Notwithstanding Section 19.4(b) below, the Parties agree that [***].

85 of 122
14.10 The Parties acknowledge and agree that an executed copy of the [*] between Genmab and [*] (the [*]) has been disclosed by or on behalf of Genmab to Biontech pursuant to a letter agreement to the Prior Collaboration Agreement dated 4 June 2021 under and subject to the terms of [*] between [*], Genmab US, Inc. and Biontech. Notwithstanding any other provision in this Agreement or such [*], the Parties acknowledge and agree that Biontech: [*]

14.11 Survival. The terms of this Section 14 shall survive termination or expiry of this Agreement and shall continue in full force and effect for as long as the Confidential Information remains confidential.

15. DATA PROTECTION
The Parties acknowledge and agree that they entered into a data processing agreement dated 13 September 2019 in relation to the processing of personal data obtained in connection with the performance of certain clinical trials under this Agreement. The Parties shall enter into a new data protection agreement on the Execution Date or as soon as practicable thereafter (in any case prior to the Parties sharing any personal data pursuant to this Agreement that is not covered by the terms of the existing data processing agreement between the Parties), the terms of which shall apply to the processing of any personal data pursuant to the terms of, or relating to, this Agreement (including without limitation the Research Plan, Development Plan or Commercialization Plan, as applicable) (the Data Protection Agreement) and which shall replace the existing data processing agreement between the Parties. In the event of any conflict or inconsistency between the provisions of this Agreement and the provisions of the Data Protection Agreement, the provisions of the Data Protection Agreement shall take precedence to the extent of the conflict or inconsistency.

16. REPRESENTATIONS AND WARRANTIES
16.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party that:
(a) it has the legal right to enter into and deliver this Agreement and constitutes the valid and binding obligation of each Party;
(b) the execution, delivery and performance of this Agreement as well as the licenses granted hereunder do not conflict with any agreement, instrument or understanding, oral or written, to which such Party may be bound.

16.2 Biontech Representations and Warranties. Biontech represents, warrants and undertakes that as of the Effective Date:
(a) it has the right to grant the licenses granted herein;
(b) the Biontech Technology licensed hereunder is free and clear of any security interests, claims, encumbrances or charges of any kind;
(c) it has not assigned and/or granted licenses, nor shall it assign and/or grant licenses under the Biontech Technology to any Third Party that would restrict or impair the rights granted to Genmab hereunder;

(d) to its actual knowledge no Third Party has infringed the Biontech Technology;

(e) it has not received any written notice of (i) any claim that any Patent Right or trade secret owned or controlled by a Third Party would be infringed or misappropriated by the development, manufacture, use, sale, offer for sale or importation of Biontech Antibodies or LCA Products or Unilateral Products containing Biontech Antibodies, or (ii) any threatened administrative proceedings or litigation seeking to invalidate or otherwise challenge the Biontech Patents;

(f) none of the Biontech Patents are the subject of any pending re-examination, opposition, interference or litigation proceedings; and

(g) to the best of its knowledge it has provided all the necessary licenses under the Biontech Technology herein to ensure the anticipated Development and Commercialization of LCA Products and the development and commercialization of Unilateral Products.

(b) Biontech is the sole legal and beneficial owner of the [***], including without limitation all and any rights, title and interest in any intellectual property rights subsisting therein, and that Biontech has complied with, and for the duration of the Term will comply with, all and any obligations, including without limitation payment obligations, to [***] as required for Biontech to retain the full legal and beneficial ownership of the [***].

16.3 Genmab Representations and Warranties. Genmab represents and warrants that as of the Effective Date:

(a) it has the right to grant the licenses granted herein;

(b) the Genmab Technology licensed hereunder is free and clear of any security interests, claims, encumbrances or charges of any kind;

(c) it has not assigned and/or granted licenses, nor shall it assign and/or grant licenses under the Genmab Technology to any Third Party that would restrict or impair the rights granted to Biontech hereunder;

(d) to its actual knowledge no Third Party has infringed the Genmab Technology;

(e) it has not received any written notice of (i) any claim that any Patent Right or trade secret owned or controlled by a Third Party would be infringed or misappropriated by the development manufacture, use, sale, offer for sale or importation of the Genmab Antibodies, LCA Products or Unilateral Products containing Genmab Antibodies, the DuoBody Platform, or the [***] Technology (the DuoBody Platform and the [***] Technology as used with the preferred mutation and embodiments) or (ii) any threatened administrative proceedings or litigation seeking to invalidate or otherwise challenge the Genmab Patents;
none of the Genmab Patents are the subject of any pending re-examination, opposition, interference or litigation proceedings; and

to the best of its knowledge it has provided all the necessary licenses under the Genmab Technology herein to ensure the anticipated Development and Commercialization of LCA Products or the development and commercialization of Unilateral Products.

16.4 **Covenant.** Each Party covenants to the other Party that it will not include any additional intellectual property rights owned or controlled by it or its Affiliates not currently included in the licenses granted under this Agreement in any Clinical Candidate or LCA Product without the prior written consent of the other Party. Notwithstanding the foregoing, if such consent is not sought or obtained, then any additional intellectual property rights unilaterally included by a Party shall be licensed to the other Party on a free and perpetual basis for use in the applicable Clinical Candidate, LCA Product or Unilateral Product.

16.5 **Disclaimers.** The Parties acknowledge and agree that the research and development to be conducted under this Agreement is experimental in nature, and that neither Party can guarantee a successful outcome thereof. Except as expressly provided in this Agreement, the know-how, Confidential Information and intellectual property rights provided by each Party are provided “as is” and except as otherwise expressly set forth herein, neither Party makes any representations or extends any warranties of any kind, either express or implied, to the other Party, and each Party hereby disclaims all implied warranties, including without limitation warranties of merchantability, fitness for a particular purpose or non-infringement.

17. INDEMNITY AND LIMITATION OF LIABILITY

17.1 **Indemnity for Unilateral Products**

(a) With respect to Unilateral Products, each Party shall defend, indemnify and hold harmless the other Party, its Affiliates and their respective directors, officers, employees and agents (collectively, the *Indemnitees*) from and against all liabilities, losses, damages, and expenses, including without limitation reasonable attorneys’ fees and costs (collectively, the *Liabilities*) incurred as a result of any Third Party claims, suits, actions, terminations or demands (collectively, the *Claims*) that result from (a) the material breach of any material provision of this Agreement by the indemnifying Party, including [***] made by such Party in this Agreement, or (b) the gross negligence, recklessness or willful misconduct of the indemnifying Party its Affiliates, employees, agents, Sublicensees or Approved Subcontractors in connection with the performance of its obligations hereunder.

(b) Genmab shall defend, indemnify and hold harmless the Biontech Indemnitees from and against all Liabilities resulting from all Claims that are incurred as a result of the development, manufacture or commercialization of Genmab Unilateral Products by Genmab, its Affiliates, Sublicensees or Approved Subcontractors; except to the extent such Liabilities must be indemnified by Biontech pursuant to Sections 17.1(a).
Biontech shall defend, indemnify and hold harmless the Genmab Indemnitees from and against all Liabilities resulting from all Claims that are incurred as a result of the development, manufacture or commercialization of Biontech Unilateral Products by Biontech, its Affiliates, Sublicensees or Approved Subcontractors; except to the extent such Liabilities must be indemnified by Genmab pursuant to Sections 17.1(a).

17.2 Indemnity for LCA Products

(a) Each Party hereby agrees to indemnify, defend, and hold harmless the other Party’s Indemnitees from and against any and all Liabilities, incurred as a result of any Claims relating to the manufacture, use, handling, storage, Development, Commercialization or other disposition of any LCA Product by the indemnifying Party, its Affiliates, employees, agents, Sublicensees or Approved Subcontractors, but only to the extent such Claims result from: (a) the gross negligence, recklessness or willful misconduct of the indemnifying Party, its Affiliates, employees, agents, Sublicensees or Approved Subcontractors; or (b) any material breach by the indemnifying Party of any material provision of this Agreement, including [***] made by such Party in this Agreement; except, in each case, to the extent of any such Claim resulting from the gross negligence or willful misconduct of the Indemnitees.

(b) Except for those Claims subject to Section 17.2(a), the Parties shall share equally any Liabilities in connection with any Claim brought against either Party by a Third Party resulting directly or indirectly from the manufacture, use, handling, storage, Development, Commercialization or other disposition of any given LCA Product.

(c) If either Party receives notice of a Claim with respect to any LCA Product, such Party shall inform the other Party in writing as soon as reasonably practicable. The Parties shall confer through the Joint Steering Committee how to respond to the Claim and how to handle the Claim in an efficient manner. In the absence of such an agreement, each Party shall have the right to take such action as it deems appropriate, subject to Section 17.4.

(d) Notwithstanding the foregoing, defense against Infringement Attacks shall be solely subject to Section 13.

17.3 Indemnity for Proprietary Combination Products. Subject to Section 13.7 and Exhibit 12, each Developing Party hereby agrees to indemnify, defend, and hold harmless the other Party’s Indemnitees from and against any and all Liabilities, incurred as a result of any Claims relating to the manufacture, use, handling, storage, development, commercialization or other disposition of the relevant Proprietary Combination Product by the Developing Party, its Affiliates, employees, agents, sublicensees or subcontractors (including, without limitation, any intellectual property infringement claims brought by any Third Party relating thereto), except to the extent such Claims result from: (a) [***] or (b) [***].

89 of 122
17.4 **Procedure.** A Party (the **Indemnified Party**) that intends to claim indemnification under this Section 17 shall promptly provide notice to the other Party (the **Indemnitor**) of any Liability or action in respect of which the Indemnified Party intends to claim such indemnification, which notice shall include a reasonable identification of the alleged facts giving rise to such Liability, and the Indemnitor shall have the right to control and participate in, and, to the extent the Indemnitor so desires, jointly with any other Indemnitor similarly noticed, to assume the defense thereof with counsel selected by the Indemnitor. However, notwithstanding the foregoing, the Indemnified Party shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnified Party, unless the representation of such Indemnified Party by the counsel retained by the Indemnitor would be inappropriate due to actual differing interests between such Indemnified Party and any other party represented by such counsel in such proceedings, in which case the reasonable fees and expenses shall be paid by the Indemnitor. The Indemnified Party cannot settle any Liability for which it intends to claim indemnification by the Indemnitor without the prior written consent of the Indemnitor. Any settlement of a Liability for which any Indemnified Party seeks to be indemnified, defended or held harmless under this Section 17 that could adversely affect the Indemnified Party shall be subject to prior consent of such Indemnified Party, provided that such consent shall not be withheld unreasonably.

17.5 **No Liability for Indirect Losses.** Neither Party shall be liable to the other, whether in tort, contract or otherwise, for any consequential, indirect, punitive, exemplary or incidental damages, lost profits or lost business opportunities. The provisions of this Section 17.5 shall not apply to cases of wilful misconduct, any breach of [***], or any breach of [***].

18. **OPT-OUT**

18.1 **Opt-Out Points.** No later than thirty (30) calendar days after either Proposed IND Submission or Establishment of Clinical Proof of Concept (the **Opt-Out Points**), as applicable, and on an LCA Product-by-LCA Product basis, each Party (the **Opt-Out Party**) shall have the right to provide the other Party with irrevocable notice in writing that it wishes to discontinue its participation in the further Development and Commercialization of such LCA Product (the **Opt-Out Notice**). The effective date of such opt-out (the **Opt-Out Date**) shall be the date thirty (30) days after the date of the Opt-Out Notice unless negotiations commence between the Parties pursuant to Section 18.3(b), in which case the effective date of such opt-out shall be (i) the date [***] days after the expiry of such negotiations under Section 18.3(b) or (ii) the date on which such amended version of Exhibit 1 is executed (as applicable). Upon receipt of the Opt-Out Notice, the other Party shall, within thirty (30) days following its receipt of the Opt-Out Notice, notify the Opt-Out Party in writing whether or not it elects to assume sole responsibility for, and all costs and obligations of, the continued Development and Commercialization of such LCA Product on the pre-defined terms set forth in Exhibit 1.
18.2 Postponement of Opt-Out. Only applicable for opt-out in connection with Establishment of Clinical Proof of Concept, the Parties may agree in writing to postpone the window, within which a Party can opt-out of the Development, in order to perform an additional clinical trial. The Parties agree and acknowledge that the pre-defined financial terms for opt-out at Establishment of Clinical Proof of Concept will remain applicable for the agreed postponed opt-out point.

18.3 Option of Other Party to Continue Development as Unilateral Product.

(a) If the other Party elects to assume sole responsibility for, and all costs and obligations of, the continued Development and Commercialization of the LCA Product on the pre-defined financial terms in Exhibit 1, then the LCA Product shall become a Unilateral Product and Section 18.5 shall apply.

(b) If the other Party is willing to assume sole responsibility for, and all costs and obligations of, the continued Development and Commercialization of such LCA Product but is not willing to accept such pre-defined financial terms in Exhibit 1, it shall notify the Opt-Out Party accordingly in writing prior to the Opt-Out Date. In such event, the Parties shall negotiate in good faith alternative terms on the basis of which the other Party is willing to assume sole responsibility for, and all costs and obligations of, the continued Development and Commercialization of such LCA Product. If the Parties are able to agree on such alternative terms within [***] days from the date of the Opt-Out Notice, the Parties shall agree and execute an amended version of Exhibit 1 for such LCA Product and Section 18.5 shall apply. If the Parties are not able to agree on such alternative terms within such [***] day time period, the other Party shall have the option to notify the Opt-Out Party within [***] days from the end of such [***] day time period that it wishes to assume sole responsibility for, and all costs and obligations of, the continued Development and Commercialization of such LCA Product on the pre-defined terms set forth in Exhibit 1, in the event of any such timely notification by the other Party, Section 18.5 shall apply. Otherwise, the LCA Product shall be considered a Ceased Product and Section 18.4 shall apply. For clarity, the Parties acknowledge and agree that during the period from the date of the Opt-Out Notice until the Opt-Out Date, the Parties shall continue to Develop such LCA Product in accordance with the terms of this Agreement.

18.4 Ceased Product.

An LCA Product shall become a Ceased Product, if and when (i) upon receipt of an Opt-Out Notice the other Party either notifies the Opt-Out Party that it does not elect to assume sole responsibility for, and all costs and obligations of, the continued Development and Commercialization of the respective LCA Product or does not notify the Opt-Out Party in writing within thirty (30) days of the date of the Opt-Out Notice that it wishes to assume sole responsibility for, and all costs and obligations of, the continued Development and Commercialization of the respective LCA Product, or if negotiations commence between the Parties pursuant to Section 18.3(b) but are unsuccessful, within [***] days of the expiry of such negotiations, or (ii) in any other scenario under which an LCA Product shall be considered a Ceased Product and/or which refers to this Section 18.4 pursuant to this Agreement. With respect to any Ceased Product:
(a) the Parties shall decide on whether or not to attempt a joint Divestment pursuant to Section 18.9. If the Divestment of a Ceased Product fails, or the Parties jointly decide not to attempt to Divest, the exclusivity obligations under Section 8 shall no longer apply to such Ceased Product or the relevant Target Combination; and

(b) both Parties shall be released from any further Development and funding obligations under this Agreement in respect of such Ceased Product, provided they shall work together to ensure that any ongoing activities related to a Ceased Product are properly wound down, and shall share costs related to such winding down, if any.

18.5 Continuation of Development and Commercialization by other Party. If a party elects to assume sole responsibility for, and all costs and obligations of the continued Development and Commercialization of the LCA Product (the Continuing Party), whether on the pre-defined terms set forth in Exhibit 1, or on other terms agreed with the Opt-Out Party pursuant to Section 18.3(b), then:

(a) such LCA Product will become a Unilateral Product;

(b) the Continuing Party will be entitled to continue the development and commercialization of the Unilateral Product in its sole discretion and Sections 3 and 4 shall no longer apply, provided that the Continuing Party shall use Commercially Reasonable Efforts to further develop and commercialize the Unilateral Product, including without limitation to achieve filing of the first IND for such Unilateral Product within [***] years after selection of the respective Clinical Candidate according to Section 2.10. The Continuing Party may extend the date by which the first IND for such Unilateral Product should be filed by [***] year by paying to the other Party [***]. Such payment shall be made no later than [***] years after selection of the respective Clinical Candidate according to Section 2.10. If the Continuing Party materially breaches its obligations under this Section 18.5(b) and fails to cure such breach within [***] days following its receipt of written notice thereof from the Opt-Out Party, the Opt-Out Party shall have the right, exercisable by written notice to the Continuing Party, to request that the Unilateral Product as well as all rights and data relating thereto shall be Divested through a Joint Divestment Process;

(c) the Continuing Party may terminate at any time in its sole discretion the development and/or commercialization of the Unilateral Product by written notice to the Opt-Out Party. Such termination shall not constitute a breach of applying Commercial Reasonable Efforts as set forth in Section 18.5(b). In the event of any such termination the Unilateral Product shall become a Ceased Product and Section 18.4 shall apply;
(d) all rights and obligations of the Opt-Out Party under this Agreement with respect to the Unilateral Product will end except for the Opt-Out Party’s continuing obligations under Sections 2.7, 2.8, 3.6 (to the extent it refers to Sections 2.7 and 2.8) and 14 or otherwise provided for in this Section 18.5 or Exhibit 1; in particular, the licenses set forth in Section 12.2 and Section 12.4 will terminate, and will be replaced by the licenses set forth in Section 18.6.

(e) the Collaboration IP solely relating to the Unilateral Product will be assigned to the Continuing Party in accordance with Section 12.1(g);

(f) the prosecution, maintenance, enforcement and defense of Patent Rights solely relating to the Unilateral Product will be subject to Sections 12.10(a), 12.10(c), 12.12(a), 12.12(c), 13.4 and 13.5;

(g) the terms and conditions set forth in Exhibit 1 will apply (except to the extent the Parties have agreed on different financial terms pursuant to the scenario set forth in Section 18.3);

(h) promptly after the Continuing Party’s election, the Parties will work together to transfer and assign all regulatory documents, contracts, materials and information related to the Unilateral Product to the Continuing Party or its designees to the extent necessary for the Continuing Party to assume such sole responsibility;

(i) the Opt-Out Party will not be refunded or repaid any amounts it has paid for the Development of such former LCA Product; and

(j) from the date of the Opt-Out Notice, the Opt-Out Party shall provide development, consultation or support work for a Unilateral Product of the Continuing Party, as reasonably requested by the Continuing Party, and the Continuing Party shall pay for such work at the then current annual FTE Fee as set forth in Exhibit 1.

18.6 Licenses for Unilateral Products.

(a) License to Genmab for Unilateral Products. On a Genmab Unilateral Product-by-Genmab Unilateral Product basis and subject to the terms of this Agreement, Biontech hereby grants to Genmab a royalty bearing (subject to the terms and conditions set forth in Exhibit 1) license under the Biontech Technology, with the right to sublicense (through multiple tiers), to develop, have developed, make, have made, import, use, offer for sale, have sold and sell Genmab Unilateral Products within the Field in the Territory. The license for a Genmab Unilateral Product shall be exclusive in accordance with Section 9.3. For avoidance of doubt, Biontech shall bear all and any costs, fees, royalties and other payments payable to [*] relating to Biontech’s [*] identified in [*] as well as [*] and such payments shall not be included in the calculation of Shared Costs.
(b) **Genmab’s Rights to Sublicense.** Genmab shall have the right to grant a sublicense of the license granted pursuant to subsection (a) above to any Affiliate or other Third Party, provided that Genmab agrees to contractually obligate any Sublicensee of a Genmab Unilateral Product to make all payments due to Biontech pursuant to this Agreement, as well as to comply with all terms of this Agreement applicable to Genmab. For the sake of clarification, such payments shall be made to Genmab and not directly to Biontech. Genmab shall also require any such Sublicensee to agree in writing to keep books and records and permit either Genmab or Biontech or both to audit the information concerning such books and records in accordance with the terms of this Agreement. If one of the Parties conducts such an audit of the books and records of a Sublicensee without the other Party’s participation, the Party conducting the audit shall upon the other Party’s request share the results of such audit with such other Party. In addition, a sublicense to an Affiliate must provide that it will automatically terminate if the relevant Sublicensee ceases to be an Affiliate of Genmab. For sublicenses permitted hereunder, Genmab shall (a) notify Biontech of each sublicense granted (both to Affiliates and Third Parties) hereunder, and (b) provide Biontech with the name and address of each Sublicensee (both Affiliates and Third Parties) and a description of the rights granted by each Sublicensee.

(c) **License to Biontech for Unilateral Products.** On a Biontech Unilateral Product-by-Biontech Unilateral Product basis and subject to the terms of this Agreement, Genmab hereby grants to Biontech a royalty bearing (subject to the terms and conditions set forth in Exhibit 1) license under the Genmab Technology, with the right to sublicense (through multiple tiers), to develop, have developed, make, have made, import, use, offer for sale, have sold and sell Biontech Unilateral Products [***] within the Field in the Territory. The license for a Biontech Unilateral Product shall be exclusive in accordance with Section 9.3. The licenses granted to Biontech hereunder with regards to the DuoBody Platform are only granted for the [***]. Use of other [***] under the DuoBody Platform can only take place upon Genmab’s prior written consent. The license granted under the [***] Technology is to [***].

(d) **Biontech’s Rights to Sublicense.** Biontech shall have the right to grant a sublicense of the license granted pursuant to subsection (c) above to any Affiliate or other Third Party, provided that Biontech agrees to contractually obligate any Sublicensee of a Biontech Unilateral Product to make all payments due to Genmab pursuant to this Agreement, as well as to comply with all terms of this Agreement applicable to Biontech. For the sake of clarification, such payments shall be made to Biontech and not directly to Genmab. Biontech shall also require any such Sublicensee to agree in writing to keep books and records and permit either Genmab or Biontech or both to audit the information concerning such books and records in accordance with the terms of this Agreement. If one of the Parties conducts such an audit of the books and records of a Sublicensee without the other Party’s participation, the Party conducting the audit shall upon the other Party’s request share the results of such audit with such other Party. In addition, a sublicense to an Affiliate must provide that it will automatically terminate if the relevant Sublicensee ceases to be an Affiliate of Biontech. For sublicenses permitted hereunder, Biontech shall (a) notify Genmab of each sublicense granted (both to Affiliates and Third Parties) hereunder, and (b) provide Genmab with the name and address of each Sublicensee (both Affiliates and Third Parties) and a description of the rights granted and the territory covered by each Sublicensee.
18.7 [***]

18.8 Exclusions for [***] and Joint Combination Products.

(a) [***]

(b) Notwithstanding Section 3.12, a Joint Combination Product as a whole may not become a Unilateral Product under this Agreement and the terms of this Section 18 shall not apply to a Joint Combination Product as a whole.

18.9 Joint Divestment Process. In the event that both Parties wish to opt-out of Development or Divest their respective ownership shares of a certain LCA Product, the Parties may jointly decide to initiate a Divestment process (the Joint Divestment Process), which shall be performed by the Parties as follows:

(a) Both Parties shall upon initiation of the Joint Divestment Process be released from any further research, Development and funding obligation under this Agreement, provided they shall work together to ensure that any ongoing activities related to the LCA Product to be Divested are properly wound down to the extent applicable, and shall share costs related to such winding down, if any.

(b) Unless otherwise agreed by the Parties at the time of initiation of the Joint Divestment Process, each Party shall designate a divestment executive (Divestment Executive) who shall not be a Joint Steering Committee member, and who shall be the point of contact for such Parties in the Joint Divestment Process and who shall report to the Joint Steering Committee.

(c) The Parties may engage a Third Party advisor, on terms acceptable to both Parties, to coordinate the Joint Divestment Process for the purpose of licensing rights to the LCA Product. The Divestment Executives and the Third Party advisor shall present to the Joint Steering Committee for approval detailed criteria for evaluating, comparing and selecting potential offers, which shall include financial and nonfinancial factors (Bidding Criteria).

(d) Neither Party may [***].

(e) The Parties shall use Commercially Reasonable Efforts to maximize the value obtained in the Joint Divestment Process.

(f) The Joint Steering Committee shall unanimously decide on which offer to accept under the Joint Divestment Process, using the Bidding Criteria. Once the Joint Steering Committee has decided which offer to accept, the Parties shall together appoint an external legal counsel to handle, on behalf of both Parties and at a cost equally shared the drafting, negotiation and finalization of the agreement with the Third Party that made the winning offer. Both Parties shall be signatories to the agreement with such Third Party.
If the Joint Divestment Process has not been finalized within [***] months after its initiation, the Parties shall discuss in good faith the terms and conditions for continuing the Joint Divestment Process, or for continuing the Development of the LCA Product, or any alternative solution, including without limitation the winding-up of the Development of the LCA Product.

19. TERM AND TERMINATION

19.1 Term. This Agreement shall become effective on the Effective Date and shall continue until the date that is the later of (i) the last to expire Royalty Term for a Unilateral Product and, (ii) when no LCA Products, Joint Combination Products or Proprietary Combination Products are being developed and/or commercialized any longer, unless terminated earlier in accordance with the provisions of this Agreement (the "Term").

19.2 Termination for Material Breach. Either Party may terminate this Agreement in its entirety or on an LCA Product-by-LCA Product and/or Unilateral Product-by-Unilateral Product basis at any time by written notice to the other Party with immediate effect if the other Party materially breaches any material provision of this Agreement and fails to cure such breach within [***] days following its receipt of written notice thereof from the terminating Party.

19.3 Termination for Insolvency. Either Party may terminate this Agreement in its entirety at any time by written notice to the other Party with immediate effect if the other Party becomes insolvent, is compelled to file bankruptcy or is determined otherwise imminently subject to control by a bankruptcy trustee or its equivalent to the laws of the jurisdiction in which such Party is doing business. Notwithstanding the foregoing, the Parties intend for this Agreement and the licenses granted herein to remain in full force and effect so long as the non-insolvent Party remains in material compliance with the terms and conditions hereof.

19.4 Effect of Expiration and Termination

(a) Except where explicitly provided within this Agreement, termination of this Agreement (whether in its entirety or with respect to an LCA Product and/or Unilateral Product) for any reason, or expiration of this Agreement, will not affect any: (i) obligations, including without limitation payment of any royalties or other sums which have accrued as of the effective date of termination or expiration, and (ii) rights and obligations which, from the context thereof, are intended to survive termination or expiration of this Agreement, including without limitation the provisions of Sections 1, 2.7, 3.6 (to the extent it refers to Section 2.7), 10.14, 10.15, 12.13, 13 (as to actions arising during the term of this Agreement or in the course of a Party practicing any licenses retained by such Party thereafter), 14, 17, 19.4(a) and 20.
Upon termination of this Agreement partly or wholly for any reason, save as expressly provided herein, all licenses granted to each of the Parties in respect of the affected terminated LCA Product(s) and/or Unilateral Product(s), and all sublicenses granted to Affiliates by a Party hereunder in respect of the affected terminated LCA Product(s) and/or Unilateral Product(s) will immediately cease and terminate. In the event the termination is to this Agreement in its entirety or else in respect of the affected terminated LCA Product(s) and/or Unilateral Product(s), the Parties shall promptly return to one another or destroy all Confidential Information of the other Party and antibodies and other materials created under the Prior Agreement or this Agreement that are in a Party’s or its Affiliates’ possession or control in respect of the affected terminated LCA Product(s) and/or Unilateral Product(s). The Parties shall jointly decide how a termination of this Agreement partly or wholly shall affect any Joint Patents.

19.5 Rights of Sublicensees. Upon the termination of this Agreement, any sublicenses granted by a Party to Third Parties hereunder shall survive, provided that each sublicensee is then in full compliance with its sublicense and promptly agrees in writing to be bound by the applicable terms of this Agreement and agrees to pay directly to the other Party or the Parties, as applicable, the same amounts that would have been due to such other Party under this Agreement with respect to such sublicense had this Agreement not been terminated.

19.6 Winding Down. Following expiration or termination of this Agreement for any reason, to the extent not prohibited by Applicable Law and unless otherwise agreed by the Parties, the Parties shall wind down any clinical trials that are underway in respect of the terminated LCA Product and/or Unilateral Product, taking into account the health and safety of the subjects enrolled therein and Good Clinical Practice. In the event that a Party is Commercializing LCA Products and/or commercializing Unilateral Products under this Agreement, and in accordance with the foregoing provisions of this Section 19.6, a license is terminated then such Party shall be entitled to, and the licenses shall be deemed to survive to the extent necessary for such Party to wind down the activities in an orderly manner, including without limitation the right to sell off inventory, but in no event for a period longer than six (6) months from the effective date of termination.

19.7 Force Majeure. No Party (or any of its Affiliates) shall be held liable or responsible to the other Party (or any of its Affiliates), or be deemed to have defaulted under or breached this Agreement, for failure or delay by such Party in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party (or any of its Affiliates), including without limitation fire, floods, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, acts of God, earthquakes, epidemics, pandemics or omissions or delays in acting by any governmental authority (collectively, ‘Events of Force Majeure’); provided, however, that the affected Party shall promptly advise the other Party of the existence of such Event of Force Majeure and shall exert all Commercially Reasonable Efforts to eliminate, cure or overcome any such Event of Force Majeure and to resume performance of its obligations promptly. Notwithstanding the foregoing, to the extent that an Event of Force Majeure continues for a period in excess of
[*] months, the affected Party shall promptly notify in writing the other Party of such continued Event of Force Majeure and within [*] month of the other Party’s receipt of such notice, the Parties shall negotiate in good faith either (i) a resolution of the Event of Force Majeure, if possible, (ii) an extension by mutual agreement of the time period to resolve, eliminate, cure or overcome such Event of Force Majeure, (iii) an amendment of this Agreement to the extent reasonably possible, or (iv) an early termination of this Agreement. If a solution under (i) to (iv) has not been reached after [*] months of the other Party’s receipt of such notice, then the Party not affected shall be entitled to give notice to the affected Party to terminate this Agreement, specifying the date (which shall not be less than [*] calendar days after the date on which the notice of termination is given) on which termination will take effect. Such a termination notice shall be irrevocable, except with the consent of both Parties, and upon termination the provisions of Section 19.4 shall apply.

20. GENERAL PROVISIONS

20.1 Notices. All notices, requests and other formal communications shall be made in writing and shall be delivered or sent in each case to the respective address specified below:

If to Genmab: Genmab A/S
[*]
[*]
[*]
[*]
[*]

If to BioNTech: BioNTech SE
[*]

Each Party shall immediately notify the other Party in the event of any changes of its address set forth above. Any notice given to a Party under or in connection with this Agreement shall be deemed to have been received at the time the notice is delivered to the relevant Party’s address set forth above.
20.2 **Insurance.** During the Term and thereafter for the period of time required below, each Party shall maintain on an ongoing basis comprehensive general liability insurance in the minimum amount of [***] per occurrence and [***] annual aggregate combined single limit for bodily injury and property damage liability. Commencing not later than [***] days prior to the first use in humans of any LCA Product or Genmab Unilateral Product and thereafter for the period of time required below, Genmab shall obtain and maintain during respective clinical studies on an ongoing basis products liability insurance (including without limitation contractual liability coverage on Genmab’s indemnification obligation under this Agreement) in the amount of at least [***] per occurrence and at least [***] annual aggregate combined single limit for bodily injury and property damage liability. Commencing not later than [***] days prior to the first use in humans of any LCA Product or Biontech Unilateral Product, and thereafter for the period of time required below, Biontech shall obtain and maintain during respective clinical studies on an ongoing basis products liability insurance for clinical studies (including without limitation contractual liability coverage on Biontech’s indemnification obligations under this Agreement) in the amount of at least [***] per occurrence and at least [***] annual aggregate combined single limit for bodily injury and property damage liability.

Upon the Effective Date and not later than [***] days prior to the first use in humans of the first LCA Product, Genmab Unilateral Product or Biontech Unilateral Product, as the case may be, each Party shall provide to other Party a certificate(s) evidencing all required coverage hereunder. Each Party shall maintain such insurance coverage without interruption during the Term and for a period of at least [***] years thereafter. Each Party shall, at the request of the other Party, provide the other Party at least [***] days’ prior written notice of any cancellation or material change in the insurance policy. For the avoidance of doubt, the term, “product liability insurance” as used in this Section 20.2 shall not include clinical trial insurances; the Parties will each obtain and maintain clinical trial insurance to the extent required by Applicable Law.

20.3 **Entire Agreement.** This Agreement, including without limitation the Exhibits to this Agreement, represent the entire understanding between the Parties with respect to the subject matter hereof, and supersede and extinguish all previous oral or written communication or agreements, and all contemporaneous oral communication and agreements between the Parties with respect to the subject matter hereof, including without limitation the Prior Collaboration Agreement and Side Letters, but excluding the Continuing Side Letters (which shall, for clarity, continue in full force and effect). For the avoidance of doubt, the termination or expiry of the Continuing Side Letters shall not affect the duration, validity or enforceability of this Agreement and vice versa.

20.4 **Accrued Obligations.** Termination or expiration of this Agreement (or the extinction of the Prior Collaboration Agreement or any Side Letter pursuant to Section 20.3) shall not release either Party from any obligation or liability which, at the time of such termination or expiration (or extinction), has already accrued to the other Party or which is attributable to a period prior to such termination or expiration (or extinction).

20.5 **Form Requirement.** This Agreement may only be amended, modified or supplemented by the Parties pursuant to a written instrument signed by both of the Parties. The same applies to this Section 20.5.
20.6 **Assignment.** Neither Party may assign, transfer or delegate its contractual rights and obligations or parts thereof under this Agreement without the prior written consent of the other Party, except for permitted subcontracting and provided, however, that either Party may, without such consent, assign this Agreement and all of its rights and obligations hereunder (i) to any Affiliate or (ii) in connection with the transfer or sale of all or substantially all of its business to which this Agreement relates, or in the event of its merger, consolidation, or other similar transaction. To the extent that any such assignment expressly permitted in the previous sentence also comprises the transfer of contractual obligations or parts thereof under this Agreement, both of the Parties shall enter into an appropriate novation agreement with such Affiliate or Third Party under which such Affiliate or Third Party assumes such contractual obligations. For clarification, any assignment to Third Parties which is not expressly allowed above requires the approval of the other Party, which approval shall not be withheld unreasonably if the Third Party assignee assumes all rights and obligations of this Agreement.

20.7 **Profit Sharing Rights.** Either Party may transfer its share of the Shared Profits hereunder to any Affiliate or Third Party (including without limitation for purposes of providing security to investors or financing parties), provided that the transferring Party shall remain Party to this Agreement and shall remain bound by all obligations hereunder, and that the non-transfering Party shall not be obligated to make any payment directly to, or perform any other obligation directly towards, the receiving Affiliate or Third Party.

20.8 **Severability.** If any provision of this Agreement is found to be invalid or otherwise unenforceable, in whole or in part, the validity of the remainder of this Agreement shall not be affected. Furthermore, the Parties agree that the invalid or unenforceable provision or part thereof shall be superseded by an adequate provision that, to the legally permitted extent, comes closest to what the Parties would have desired at the time of conclusion of this Agreement had they considered the issue concerned.

20.9 **Independent Contractor.** Nothing in this Agreement shall create, or be deemed to create, a partnership, joint venture, or the relationship of principal and agent or employer and employee between the Parties. Each Party agrees to perform under this Agreement solely as independent contractor.

20.10 **Dispute Resolution.** Any dispute arising between the Parties in connection with this Agreement shall be referred to the Joint Research Committee or the competent Joint Steering Committee or Joint Commercialization Committee, as applicable. Save as set out in Section 11.3(e), if the competent committee is unable to negotiate in good faith and settle the dispute within [***] days after being requested to do so, either Party may submit the dispute to the Parties’ [***] who shall meet in order to attempt to resolve the dispute. If the dispute is not settled, at the latest, within [***] weeks from the date that the dispute has been escalated to the [***], either Party may pursue legal action in accordance with Section 20.11 below. For the avoidance of doubt, if the dispute is with respect to an amendment of the Research Plan or any Development Plan, the current version of such Research Plan or Development Plan shall remain in effect until the dispute is finally settled.
20.11 **Governing Law, Arbitration**

(a) This Agreement and any dispute or claim (including without limitation non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation shall be governed by and construed in accordance with the laws of England and Wales without reference to its conflict of laws provisions.

(b) All disputes arising out of or in connection with this Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with said Rules. The place of the Arbitration Tribunal shall be London, England. The language of the arbitration proceeding shall be English.

(c) Notwithstanding anything to the contrary in this Agreement, each Party shall be entitled to specific performance of the obligations of the other Party under this Agreement and may seek injunctive relief (to the extent permissible by Applicable Law) to protect its Confidential Information and intellectual property rights in any court of competent jurisdiction.

20.12 **Counterparts and DocuSign** This Agreement may be signed in any number of counterparts with the same effect as if the signatures to each counterpart were upon a single instrument, and all such counterparts together shall be deemed an original of this Agreement. The Parties agree that this Agreement may be signed using a DocuSign electronic signature. Such electronic signature is the legally binding equivalent to a Party’s handwritten signature and it has the same validity, enforceability and meaning as a handwritten signature and the Parties hereby waive any objection to the contrary.

[End of Agreement – Signatures on the following page]
IN WITNESS WHEREOF, authorized representatives of the Parties have duly executed this Agreement as of the Effective Date

For Genmab A/S:

By: /s/ Anthony Mancini
Name: Anthony Mancini
Title: EVP & COO

For BioNTech SE:

By: /s/ Jens Holstein
Name: Jens Holstein
Title: CFO

By: /s/ Sean Marett
Name: Sean Marett
Title: CBO/CCO
1. **Financial Terms**

1.1 **Milestone Payments**

(a) **Allocation.** As partial consideration for the licenses, rights and privileges granted to it hereunder, a Continuing Party shall promptly inform the Opt-Out Party of the achievement of any of the below milestones and pay to the Opt-Out Party the following milestone payments on a Unilateral Product-by-Unilateral Product basis within [***] days of the first occurrence of each event set forth below with respect to a Unilateral Product to achieve such event, whether such events are achieved by the Continuing Party, its Affiliates, or Sublicensees, as follows:

- In case of Continuing Party developing from **Selection of a Clinical Candidate:**
  - [***]
  - [***]
  - [***]

- In case of Continuing Party developing from **Proposed IND Submission:**
  - [***]
  - [***]
  - [***]

- In case of Continuing Party developing from **Establishment of Clinical Proof of Concept:**
  - [***]
  - [***]
  - [***]

(b) **Clarifications.** All milestone payments shall only become due and payable once per Unilateral Product and Indication. If any of the development milestone events is achieved before the previous development milestones having become payable, the previous development milestones shall become due and payable with the achievement of such milestone event. If a development milestone has not been achieved, but the Continuing Party decides to continue the development in spite of such failure to achieve the milestone, the relevant development milestone shall be deemed to be achieved. For the avoidance of doubt, if a Unilateral Product is replaced by a Back-up Candidate only such milestones not already paid for the Unilateral Product shall become payable for the Back-up Candidate.
1.2 Royalties.

(a) Royalties Payable on Net Sales of Unilateral Products. In partial consideration for the license for a Unilateral Product granted to the Continuing Party herein, during the Royalty Term and subject to (b) below, the Continuing Party shall pay to the other Party royalties on the aggregate Net Sales of all Unilateral Products, on a country-by-country basis. Such royalties shall be paid at the following rates as set forth below:

(i) In case of Continuing Party developing from Selection of a Clinical Candidate:
   * [***]
   * [***]
   * [***]

(ii) In case of Continuing Party developing from Proposed IND Submission:
   * [***]
   * [***]
   * [***]

(iii) In case of Continuing Party developing from Establishment of Clinical Proof of Concept:
   * [***]
   * [***]
   * [***]

(b) Royalty Offsets and Reductions

(i) Subject to the royalty offset set forth in (ii) and (iii) below, the Continuing Party shall be solely responsible for paying all amounts, including without limitation any license fees, milestones and royalties owed to Third Parties by either Genmab or Biontech on account of developing and commercializing a Unilateral Product, including without limitation any royalties owed due to use of the Biontech Technology or Genmab Technology, without reduction of, or offset against, the royalties payable to the Opt-Out Party hereunder.
(ii) Notwithstanding paragraph (i) and only if Biontech has opted-out at Establishment of Clinical Proof of Concept, on a Calendar Quarter-by-Calendar Quarter and country-by-country basis, Genmab [***] for intellectual property rights that are necessary to ensure product compound improvements and overcome freedom-to-operate obstacles (excluding for the avoidance of doubt intellectual property rights necessary for manufacturing formulation or processes) with respect to a Genmab Unilateral Product against the royalties that would otherwise be payable to Biontech pursuant to paragraph 1.2(a) for such Genmab Unilateral Product. Notwithstanding anything to the contrary in this subsection (ii), in no event shall the royalty payments due and payable to Biontech pursuant to paragraph 1.2(a) with respect to a Genmab Unilateral Product in any Calendar Quarter and country be [***].

(iii) Notwithstanding paragraph (i) and only if Genmab has opted-out at Establishment of Clinical Proof of Concept, on a Calendar Quarter-by-Calendar Quarter and country-by-country basis, Biontech [***] by Biontech to Third Parties for intellectual property rights that are necessary to ensure product compound improvements and overcome freedom-to-operate obstacles (excluding for the avoidance of doubt intellectual property rights necessary for manufacturing formulation or processes) with respect to a Biontech Unilateral Product against the royalties that would otherwise be payable to Genmab pursuant to paragraph 1.2(a) for such Biontech Unilateral Product. Notwithstanding anything to the contrary in this sub-paragraph (iii), in no event shall the royalty payments due and payable to Genmab pursuant to paragraph 1.2(a) with respect to a Biontech Unilateral Product in any Calendar Quarter and country be reduced by [***].

(iv) In the event that at any time during the applicable Royalty Term, in respect to a Unilateral Product in a specific country, the following has occurred; (a) the market share of such Product is less [***] in such country in a calendar year; and (b) the decline in such market share is attributable to the marketing or sale in such country of a Generic Product of such Unilateral Product by a Third Party, the applicable royalty rate shall be reduced by [***] in such country for the remainder of the Royalty Term applicable for such Unilateral Product in such country.

(v) In the event that a Valid Patent Claim of a Patent Right covering composition of matter or method of use with respect to a Unilateral Product in the country of sale does not exist at any time during the applicable Royalty Term, the applicable royalty rate shall be [***] in such country for the remainder of the Royalty Term applicable for such Unilateral Product in such country.

(c) Reference to Certain Provisions of this Agreement. Sections 10.14 and 10.15 of this Agreement shall apply correspondingly to royalty payments. For clarity, Sections 10.16 and 10.17 of this Agreement shall apply to royalty payments.

(d) Royalty Reports, Exchange Rates
Flash reports. After the end of each Calendar Quarter, the Continuing Party shall provide to the other Opt-Out Party a "flash sales report" in order to give the Opt-Out Party an indication of the magnitude of the royalties that are likely to be due pursuant to the applicable Royalty Report described in sub paragraphs (i) and (ii) below. For clarity, each such "flash sales report" shall be provided as a courtesy estimate only and shall not be used as a basis of comparison against actual royalties due nor be considered legally binding on the Parties in any way.

Royalty Reports. During the Royalty Term, any Party paying royalties hereunder (the Paying Party) shall furnish to the other Party, with respect to each Calendar Quarter, a written report showing, on a consolidated basis in reasonably specific detail and on a country-by-country basis, (a) the Net Sales of Unilateral Products sold by the Paying Party, its Affiliates and its Sublicensees in the Territory during the corresponding Calendar Quarter on a Unilateral Product-by-Unilateral Product and country-by-country basis to calculate Net Sales; (b) the royalties payable in US Dollars, if any, which shall have accrued hereunder based upon such Net Sales of Unilateral Products; (c) the withholding taxes, if any, required by Applicable Law to be deducted in respect of such royalties; (d) the dates of the First Commercial Sale of each Unilateral Product in each country in the Territory, if it has occurred during the corresponding Calendar Quarter; and (e) the exchange rates used in determining the royalty amount expressed in Dollars (collectively the Royalty Reports).

Report Due Date. Royalty Reports and royalty payments shall be due on the day following the end of the Calendar Quarter to which such Royalty Report relates. The Parties shall keep complete and accurate records in sufficient detail to properly reflect all gross sales and Net Sales and to enable the royalties payable hereunder to be determined. The provisions on audit and dispute resolution in Sections 10.14 and 10.15 of this Agreement shall apply mutatis mutandis.

Exchange Rates. With respect to sales of Unilateral Products invoiced in US Dollars, the gross sales, Net Sales, and royalties payable shall be expressed in US Dollars. With respect to sales of Unilateral Products invoiced in a currency other than US Dollars, the gross sales, Net Sales and royalties payable shall be expressed in the currency of the invoice issued by the Party making the sale together with the US Dollars equivalent of the royalty due, calculated as described in Section 10.16 of this Agreement.

FTE Fee. A Continuing Party shall pay the Opt-Out Party at an annual rate of per FTE who performs consultation or support work for Unilateral Products in the pre-clinical phase as requested by the Continuing Party pursuant to this Agreement and an annual rate of per FTE who performs development, consultation or support work for Unilateral Products after the pre-clinical phase as requested by the Continuing Party pursuant to this Agreement (the FTE Fee). Such development, consultation or support work shall be at the
sole discretion of the Opt-Out Party. Commencing upon the [***] anniversary of the Effective Date and upon [***] anniversary thereafter, the fee will be adjusted in accordance with the percentage change over the applicable annual period in the consumer price inflation in the euro area as measured by the Harmonised Index of Consumer Prices (“HICP”).

2. **Other Terms**

2.1 **Conduct.** A Continuing Party shall comply with all Applicable Laws (including without limitation GxPs to the extent applicable) in the development and commercialization of Unilateral Products, and shall cause its Affiliates and Sublicensees to do the same.

2.2 **Funding and Progress Reports.** A Continuing Party shall be solely responsible for funding all costs of the development and commercialization of its Unilateral Product(s). A Continuing Party shall keep the other Party’s Alliance Manager informed on a quarterly basis on the progress of development as well as any milestone projections. Annually and no later than January 15 in the subsequent calendar year a Continuing Party shall send a written report on the progress of the development of its Unilateral Product(s) in the previous calendar year. Also, if the Continuing Party decides to cease development of the Unilateral Product, the other Party’s Alliance Manager shall be informed in writing thereof with [***] calendar days.

2.3 **Manufacturing.** A Continuing Party shall be responsible for all manufacturing and supply of its Unilateral Product(s).

2.4 **Regulatory.** A Continuing Party shall be solely responsible for, and shall solely own, all applications for Marketing Approval with respect to its Unilateral Product(s), and the Opt-Out Party shall, if applicable, have the obligation to transfer and assign any regulatory documents, contracts, etc. that has been assigned to it pursuant to Section 7.1(b) of this Agreement to the Continuing Party. Should a Continuing Party desire to file an IND or an application for Marketing Approval, or equivalents of the foregoing, for a Unilateral Product, the Opt-Out Party agrees to provide at the Continuing Party’s request, any and all technical information the Opt-Out Party has created or possesses that is reasonably required by the Continuing Party. The sharing of such information can be by exchange of documents and/or through telephone or personal meetings. The Continuing Party shall reimburse the Opt-Out Party for any out of pocket costs incurred by the Opt-Out Party in providing any such information or assistance pursuant to this paragraph 2.4, plus an amount equal to the then current FTE Fee for personnel engaged in such activities. If ownership of a regulatory filing for a former LCA Product cannot be assigned to a subsequent Continuing Party in any country, the Opt-Out Party shall grant to the Continuing Party a permanent, exclusive and irrevocable right of access and reference to such regulatory filing for such former LCA Product in such country.

107 of 122
2.5 Notwithstanding that a Continuing Party shall be solely responsible for the clinical development and commercialization of its Unilateral Product(s), Section 7.5 of this Agreement shall apply to the reporting of Adverse Events and Serious Adverse Events relating to such Unilateral Product(s).

2.6 Expiry of Royalty Term. Upon the expiration of the Royalty Term for a certain Unilateral Product, the Opt-Out Party shall grant, and shall by this provision be deemed to have granted, to the Continuing Party a royalty free, perpetual, worldwide, non-exclusive license to use the Joint Patents, if any, Assigned Patents, and Biontech Technology or Genmab Technology, as applicable, to make, use, sell, offer for sale and import such Biontech Unilateral Product or Genmab Unilateral Product, as applicable, with no further obligations to the Opt-Out Party.
Exhibit 3: Genmab Patents

[***]

110 of 122
Exhibit 4: Antibody Panel

<table>
<thead>
<tr>
<th>Table 1: List of all available antibodies [<em><strong>] from BioNTech ([</strong></em>] antibodies).</th>
</tr>
</thead>
<tbody>
<tr>
<td>[***]</td>
</tr>
<tr>
<td>[***]</td>
</tr>
<tr>
<td>[***]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 4: Current list of antibodies, which were identified to be agonistically targeting [<em><strong>] ([</strong></em>] antibodies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[***]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 5: Current list of antibodies, which were identified to bind to [<em><strong>], but were not shown to agonistically targeting so far ([</strong></em>] antibodies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[***]</td>
</tr>
</tbody>
</table>

111 of 122
**Table 6:** Current list of antibodies, which were identified to [***], but were not shown to agonistically targeting so far ([***] antibodies).

**Table 7:** Current list of antibodies, which were identified to [***], but were not shown to agonistically targeting so far ([***] antibodies).

**List of so far identified [***] or [***]:**

112 of 122
1. For the purposes of this Exhibit 7, the term “Cover” means, with respect to a Patent Right, that, in the absence of a license granted or a right to operate under a Valid Patent Claim of such Patent Right, the research, manufacturing, development or commercialization of a given pharmaceutical product or the practice of technology related to such a product would infringe such Valid Patent Claim.

2. Genmab acknowledges that the scope of the claims of Biontech’s patent right no. [***] as filed goes beyond the scope of the collaboration between the Parties as outlined in this Agreement. For clarity, inter alia the main claim of Biontech’s patent right no. [***] relates to [***]. This term includes [***]. In contrast, the collaboration between the Parties under this Agreement is strictly limited to the development of Collaboration Products on the basis of [***] in the Field (the Within Scope Matters). The Parties acknowledge and agree that the New Patents may Cover: (i) only Within Scope Matters, or (ii) Within Scope Matters and other subject matter (such other subject matter the Out of Scope Matters), or (iii) only Out of Scope Matters. In order to reflect the different scopes of this Agreement, the claims of Biontech’s patent right no. [***] and the New Patents, as well as the Parties’ respective contributions to the New Patents and any Collaboration IP subsisting therein, the Parties agree to deal with the New Patents and any Collaboration IP subsisting therein pursuant to the terms of this Exhibit 7.

3. Any New Patent that Covers Within Scope Matters (irrespective of whether it also Covers any Out of Scope Matters (as defined above)) shall be treated as a Joint Patent, and any inventions disclosed in a New Patent that Covers Within Scope Matters constitutes Collaboration IP (irrespective of whether the New Patent also Covers any Out of Scope Matters (as defined above)), in each case to be owned, prosecuted, maintained, defended and enforced in accordance with Section 12 of this Agreement.

4. Save as and to the extent otherwise agreed by the Parties in writing, any New Patent that solely Covers Out of Scope Matters (as defined above) shall be owned, prosecuted, maintained, defended and enforced by Biontech, in each case at Biontech’s own cost and expense.

5. Biontech shall act as Lead IP Party for the New Patents. The Parties agree, however, that the Lead IP Party may change, if relevant, dependent on the further progress of the collaboration under this Agreement, such that Genmab may be appointed as Lead IP Party for divisional application(s) where relevant.

6. Subject to paragraph 8 of this Exhibit 7 and save as and to the extent otherwise agreed by the Parties in writing, Genmab hereby grants to Biontech a perpetual, irrevocable, worldwide, exclusive, royalty-free license (including without limitation the right to sublicense through multiple tiers) under Genmab’s share of the New Patents to the extent they relate to any Out of Scope Matter to research, develop, have developed, make, have made, import, use, offer for sale, have sold and sell products which are not Collaboration Products, except that Genmab shall retain the right (including without limitation the right to sublicense through multiple tiers) to research, develop, have developed, make, have made, import, use, offer for sale, have sold and sell products based on Genmab’s DuoBody Platform and/or [***] Technology and/or other [***] technologies owned or controlled by Genmab which are not Collaboration Products.
7. Save as and to the extent otherwise agreed by the Parties in writing, Biontech hereby grants to Genmab a perpetual, irrevocable, worldwide, non-exclusive, royalty-free license (including without limitation the right to sublicense through multiple tiers) under Biontech’s share of the Out of Scope Matters of the New Patents to research, develop, have developed, make, have made, import, use, offer for sale, have sold and sell products based on Genmab’s DuoBody Platform and/or [***] Technology and/or other [***] technologies owned or controlled by Genmab which are not Collaboration Products.

8. Either Party may on a sound and reasonable basis request the other Party’s consent to the filing of divisional application(s) of any New Patent (such consent not to be unreasonably withheld, delayed or conditioned, provided that no such consent of Genmab is required if Biontech requests the filing of an Out of Scope Divisional as defined below). Any divisional patent application derived from any New Patent that covers a specific Collaboration Product shall be jointly owned by the Parties and shall be assigned in accordance with the corresponding provisions of this Agreement (including without limitation in the case of a Unilateral Product, pursuant to Section 12.1(g)).

Save as and to the extent otherwise agreed by the Parties in writing, any divisional patent application derived from any New Patent that solely covers any Out of Scope Matter (such divisional an Out of Scope Divisional) shall be assigned to Biontech. Biontech shall grant a perpetual, irrevocable, worldwide, non-exclusive, royalty-free license under the Out of Scope Divisional to Genmab (including without limitation the right to sublicense through multiple tiers) to research, develop, have developed, make, have made, import, use, offer for sale, have sold and sell products based on Genmab’s DuoBody Platform and/or [***] Technology and/or other polypeptide-based antibody-related technologies owned or controlled by Genmab which are not Collaboration Products.

9. For clarity and notwithstanding anything to the contrary in this Agreement, all rights and licenses under the New Patents are subject to the exclusivity restrictions set out in Section 8 of this Agreement.
Exhibit 12: Principles regarding Proprietary Combination Licenses

1. If the Developing Party or the Non-Developing Party, as applicable, notifies the Joint IP Committee pursuant to Section 13.7 that it deems that a Proprietary Combination License is needed to [*] or [*] a Proprietary Combination Product, then such Party shall explain its reasons for the foregoing in sufficient detail to the Joint Steering Committee, including responding to any reasonable questions which the other Party may pose in respect of the same. Following such discussion by the Joint Steering Committee, the Joint Steering Committee shall vote to determine whether or not it considers that a Proprietary Combination License is needed. For clarity, such discussion by the Joint Steering Committee and such vote shall occur prior to a Party entering into any negotiations in respect of, or executing, any Proprietary Combination License.

2. If the Joint Steering Committee decides that a Proprietary Combination License is needed, then any upfront payment(s) and any development and regulatory milestone payments paid under such Proprietary Combination License shall be shared [*] between: (i) [*]; and (ii) [*]. For clarity, in such circumstances, [*]. Royalties and any sales milestone payments paid under such Proprietary Combination License shall be shared between: (i) [*]; and (ii) [*], on a pro rata basis in accordance with the ratio of net sales of [*] on the one hand, [*], on the other hand. For example for illustrative purposes only, [*]. The Joint Steering Committee shall not unreasonably withhold its consent to any Proprietary Combination License proposed by either Party.

3. If the Joint Steering Committee cannot agree whether a Proprietary Combination License is needed, or cannot agree to the proposed timing for taking such Proprietary Combination License, in either case as a result of the Non-Developing Party voting against such Proprietary Combination License (or the timing of the same), then the Non-Developing Party shall explain the reasons for such position to the Joint Steering Committee in sufficient detail. Notwithstanding such decision, the Developing Party may take such Proprietary Combination License at any time during development, but before commercialization, of the Proprietary Combination Product, at its sole cost. Notwithstanding the foregoing, any royalties and any sales milestone payments (but excluding any developmental or regulatory milestone payments or upfront payments) paid under the Proprietary Combination License shall be shared between: (i) [*]; and (ii) [*], on a pro rata basis in accordance with the ratio of net sales of [*] on the one hand and [*] on the other hand [*].

4. If the Joint Steering Committee cannot agree whether a Proprietary Combination License is needed, or cannot agree to the proposed timing for taking such Proprietary Combination License, in either case as a result of the Developing Party voting against such Proprietary Combination License (or the timing of the same), then the Developing Party shall explain the reasons for such position to the Joint Steering Committee.
Committee in sufficient detail. If, as a result of further subsequent information, the Developing Party later believes that such Proprietary Combination License is needed, then: (i) it shall notify the Joint IP Committee again of such belief pursuant to Section 13.7; (ii) it shall explain the reasons for its revised position to the Joint Steering Committee pursuant to paragraph 1 of this Exhibit 12; (iii) the Joint Steering Committee shall determine whether a Proprietary Combination License is needed; and (iv) the terms of this Exhibit 12 shall apply to the decision of the Joint Steering Committee with respect to the same. Notwithstanding any of the foregoing in this paragraph 4, if a Third Party brings an infringement action against a Party prior to such Proprietary Combination License being entered into in any of the scenarios described above in this paragraph 4, then the Developing Party shall bear all costs incurred by the Parties in connection with such litigation (including, without limitation, all out-of-pocket costs for the Non-Developing Party provided that the Non-Developing Party has granted to the Developing Party the right to control such litigation in accordance with Section 17.4) and any settlement payments and damages (including \(\text{***}\)) (except for payments which are related to catching up on royalty payments over sales that took place prior to the relevant court decision or a Proprietary Combination License being entered into which shall be shared as described below). All sales milestone and royalty payments (including, without limitation, sales milestone payments and royalties both in respect of future net sales of the Proprietary Combination Product and in respect of net sales of the Proprietary Combination Product which occurred prior to the relevant court verdict or a Proprietary Combination License being entered into) payable under such Proprietary Combination License shall be shared between: (a) \(\text{***}\); and (b) \(\text{***}\), on a pro rata basis in accordance with the ratio of net sales of \(\text{***}\) on the one hand and \(\text{***}\) on the other hand.

5. In all cases, the Developing Party alone or both Parties may enter into such Proprietary Combination License. If only the Developing Party enters into such Proprietary Combination License, it shall ensure that the Non-Developing Party receives the benefit of a sub-license under such Proprietary Combination License in order to permit the Non-Developing Party to continue to \(\text{***}\) included in any such Proprietary Combination Product in accordance with this Agreement.
Negotiated in
Munich

on
the twenty-second of December two thousand twenty-two
- 22.12.2022 –

Before me, the undersigned Notary

with the official seat in Munich
appeared today in my offices in [***].

(1) [***], business address Steinstr. 72, 81667 Munich, known by name,
here acting not in his own name but as a sole representative authorized managing director and exempt from the restrictions of section 181
second alternative of the German Civil Code (BGB),

for Santo Service GmbH, which is registered in the Commercial Register of the Local Court of Munich under HRB 169942, with its
registered office in Munich and its business address at Steinstr. 72, 81667 Munich,
- hereinafter referred to as the “SELLER” –.

(2) [***], business address An der Goldgrube 12, 55131 Mainz, known by name,

(3) [***], business address An der Goldgrube 12, 55131 Mainz, known by name,

the persons appearing under (2) and (3) here acting not in their own name, but as managing directors authorized to jointly represent
a) for BioNTech Real Estate Verwaltungs GmbH, registered in the Commercial Register of the Local Court of Munich under HRB
245691, with its registered office in Holzkirchen, district of Miesbach, and its business address at Bergfeldstr. 9, 83607 Holzkirchen,
this in turn acting as its personally liable partner,
for BioNTech Real Estate An der Goldgrube 12 GmbH & Co. KG with its registered office in Holzkirchen, district of Miesbach, and its business address at Bergfeldstr. 9, 83607 Holzkirchen, - hereinafter referred to as “BUYER 1)“-  

b) for BioNTech Manufacturing GmbH, registered in the Commercial Register of the Local Court of Mainz under HRB 47548, with its registered office in Mainz and its business address at An der Goldgrube 12, 55131 Mainz,  

- hereinafter referred to as “BUYER 2)“-  

Pursuant to section 21 of the German Federal Code for Notaries (BNotO), the Notary certifies the aforementioned representation relationships, based on inspection of the electronic commercial register as of today.

The SELLER, BUYER 1) and BUYER 2) are called in the following also in each case a “PARTY” and together the “PARTIES”.

The NOTARY pointed out that it is legally obligated to electronically process the personal data of the PARTIES and—at the request of the relevant authorities—to pass them on.

Informed about the obligation to disclose information according to the German Money Laundering Act, the participants declared that the persons represented by them act exclusively on their own account.

The persons appeared then asked the NOTARY, with their simultaneous presence—acting as indicated—to certify the following:

2
1. THE PROPERTY

1.1. The SELLER is registered in the Land Register as the sole owner of the real property described below (hereinafter collectively referred to as the “PROPERTY”):

Land Register of Mainz at the Mainz Local Court, Sheet 27338, IV No. 1, District Mainz, Field 21, Plot 450/5, building and open areas, An der Goldgrube 12, sized indicated in the Land Register 5,359 m².

1.2. The PROPERTY is not encumbered in sections II and III of the Land Register.

1.3. SANIPharma GmbH, Ottobrunn, is currently still recorded as the owner in the Land Register. The shareholders’ meeting of SANIPharma GmbH amended the Articles of Association on November 27, 2014 and also changed the company name to “Santo Service GmbH”. The entry in the commercial register was made on January 20, 2015. This is hereby officially certified by the NOTARY on the basis of inspection in the electronic commercial register (Munich Local Court, HRB 169942). The correction of the Land Register is hereby approved and applied for.

1.4. According to Annex 1.4, the PROPERTY is not encumbered with building encumbrances; the existing building encumbrance in favor of the PROPERTY (75 parking spaces on Plot 62) is known to BUYER 1).

1.5. The NOTARY has ascertained the contents of the Land Register on the basis of inspection of electronic Land Register extracts as of today’s date and hereby confirms the completeness and correctness of the entry status reproduced in Clauses 1.1 and 1.2 at the time of inspection and that the Land Registry – on the basis of inspection of the mark table—did not have any unprocessed application for execution at that time. The register of building encumbrances was not inspected by the NOTARY.

1.6. The PROPERTY is built with an office and laboratory building. The PROPERTY is currently rented.

1.7. BUYER 1) shall take over all existing encumbrances and restrictions in the Land Register and in the register of building encumbrances created with the consent or cooperation of BUYER 1) and all present and future encumbrances and restrictions of all kinds, including the agreements under the law of obligations, which are apparent from this Purchase Contract. BUYER 1) agrees to further acquiescence and performance of all rights, duties, obligations and obligations with effect from the TRANSFER DATE without any indemnification and without any set-off against the PURCHASE PRICE 1. BUYER 1) also assumes, in accordance with the aforementioned, all existing easements and neighboring restrictions and encumbrances which are not evident from the Land Register or other registers, in particular those which are not registrable. The SELLER declares that it has no knowledge of such easements under prior law and neighboring restrictions and encumbrances.
2. **SALE**

2.1. The SELLER hereby sells to BUYER 1) accepting the same the PROPERTY together with all essential components and accessories, insofar as these are owned by the SELLER, as well as all rights and obligations associated with the PROPERTY ("PURCHASE OBJECT 1").

2.2. The SELLER sells to BUYER 2) accepting the same all movable inventory items of the office and laboratory building located on the property ("PURCHASE OBJECT 2") under guarantee of freedom from rights of third parties; the SELLER owes in this respect unencumbered transfer of possession and ownership. PURCHASE OBJECT 2 includes the movable inventory items identified in Annex 2.2.

2.3. The property of third parties (especially lessors) is excluded from the sale.

3. **PURCHASE PRICE**

3.1. The (net) purchase price for PURCHASE OBJECT 1 amounts to

\[
\text{EUR} [***] \quad \text{(in words: Euro [***])}
\]

("PURCHASE PRICE 1").

From PURCHASE PRICE 1 are attributable to:

- Land [***] EUR,
- Building [***] EUR.

3.2. The (net) purchase price for PURCHASE OBJECT 2 amounts to EUR [***]

\[(\text{in words: Euro [***]})\]

("PURCHASE PRICE 2").

3.3. PURCHASE PRICE 1 and PURCHASE PRICE 2 are hereinafter jointly referred to also as the "PURCHASE PRICE".

3.4. An increase or reduction of the PURCHASE PRICE is excluded; in particular, PURCHASE PRICE 1 is independent of the rental, location and size of PURCHASE OBJECT 1, even if a later survey should show deviations from the assumed size. This also applies to any deviations from assumed rental or usable areas.
4. SALES TAX

4.1. The PARTIES are in agreement that the sale of PURCHASE OBJECT 1 is a non-taxable sale of a business as a whole pursuant to section 1 para. 1a of the German Value Added Tax Act (UStG). PURCHASE PRICE 1 is therefore exclusive of VAT. No opinion has been obtained from the relevant tax authorities on this matter.

4.2. The SELLER declares that it is an entrepreneur within the meaning of section 2 of the German Value Added Tax Act (UStG) and that it carries on the sale within the scope of his business and that PURCHASE OBJECT 1 is therefore part of its business assets. BUYER 1) declares that it is an entrepreneur within the meaning of section 2 of the German Value Added Tax Act (UStG) and that the acquisition of PURCHASE OBJECT 1 is made in its entirety for its business and that it intends to continue the rental/leasing business. The PARTIES shall indemnify the relevant other PARTY against all disadvantages, in particular related input tax and VAT issues, which directly result from an incorrectness of the above information.

4.3. BUYER 1) is aware that in the event of a sale of a business as a whole, the adjustment period required for an input tax adjustment is not interrupted, but that BUYER 1) takes the place of the SELLER (section 15a(10) sentence 1, section 1(1a) of the German Value Added Tax Act (UStG)). Therefore, an adjustment of the input tax amounts claimed by the SELLER may also be necessary at the expense of BUYER 1) (e.g. in the event of a transition to tax-free leasing/renting of the PURCHASE OBJECT 1) or in the event of a tax-free resale).

4.4. The SELLER undertakes to provide BUYER 1) within one month after the TRANSFER DATE with all the information required for any input tax adjustment (section 15a(10) sentence 2 of the German Value Added Tax Act (UStG) in conjunction with section 22 (4) of the German Value Added Tax Act (UStG), section 15a.12 of the German Sales Tax Application Decree (USAE)), insofar as these are available to the SELLER.

4.5. Insofar as the tax authorities demand a (more extensive) adjustment pursuant to section 15a of the German Value Added Tax Act (UStG) (negative adjustment amounts) for input taxes claimed by the SELLER up to the VAT-relevant transfer date of BUYER 1) and claim against the BUYER 1) for this, the SELLER shall bear, in the internal relationship to BUYER 1), any input taxes to be refunded together with any ancillary tax payments not caused by BUYER 1) within the meaning of section 3(4) of the German Tax Code (AO) if and to the extent that the adjustment is based on a change in use after the transfer date. The aforementioned refund claims of BUYER 1) against the SELLER shall become due for payment five (5) BANKING DAYS after the due date vis-à-vis the tax office, but no later than ten (10) BANKING DAYS after the determination of the respective tax assessment notice from BUYER 1) to the SELLER. However, input tax corrections within the meaning of section 15a UStG (Value Added Tax Act) for corrections occurring after the TRANSFER DATE and caused by BUYER 1) or caused by BUYER 1) without legal obligation shall be borne by BUYER 1).
4.6. The PARTIES undertake to treat the delivery of the property vis-à-vis the competent Tax Office in the corresponding advance sales tax returns and annual sales tax returns as a business transaction not subject to sales tax as a whole (section 1 (1a) of the German Value Added Tax Act (UStG)). In this context, the PARTIES will disclose this contractual clause and all information necessary for assessing taxability to the Tax Offices.

4.7. Notwithstanding the opinion of the PARTIES that the transfer of PURCHASE OBJECT 1 is a non-taxable transaction as a whole, the SELLER already now opts for the VAT liability of the transfer of PURCHASE OBJECT 1 as follows:
   a) the SELLER hereby and today unconditionally and irrevocably waives the exemption from VAT pursuant to section 4 No. 9 para. a) of the German Value Added Tax Act (UStG) with regard to all areas of PURCHASE OBJECT 1 in accordance with section 9(1) and (3) of the German Value Added Tax Act (UStG) and opts for VAT in this respect. Accordingly, BUYER 1) owes the VAT on PURCHASE PRICE 1 opted for VAT directly to the Tax Office responsible for it; the contractual PURCHASE PRICE 1 does not include VAT.
   b) Insofar as the competent Tax Office should not recognize the waiver of the tax exemption German Value Added Tax Act (UStG) declared by the SELLER above, the SELLER shall be obliged and entitled to declare the waiver of the tax exemption to the extent legally permissible at the expense of the SELLER by means of a contractual arrangement to be notarized, if necessary after approval of the requirements of the competent Tax Office. The costs of the possibly necessary notarial supplementary deed shall be borne by the SELLER.
   c) The SELLER shall issue to BUYER 1) a proper invoice in accordance with sections 14, 14a of the German Value Added Tax Act (UStG), in which (insofar as a taxable supply of goods is concerned) the tax liability of the recipient of the service and (insofar as a tax-free supply of goods is concerned) the tax exemption of the turnover is indicated. The present Purchase Contract does not constitute an invoice for VAT purposes.

4.8. The PARTIES are aware of the provision of section 75 of the German Tax Code (AO), from which an unconditional liability of BUYER 1) may arise for any outstanding business tax liabilities of the SELLER. The SELLER declares that all of these tax liabilities have already been or will be paid. It releases BUYER 1) from any liability according to section 75 of the German Tax Code (AO) for any tax liabilities of the SELLER. The foregoing declaration shall apply mutatis mutandis to any liability of BUYER 1) for tax liabilities of the SELLER which may arise from section 1(1) sentence 3 of the German Value Added Tax Act (UStG), as well as to any liability of BUYER 1) under section 11(2) of the German Real Estate Tax Act (GrStG), according to which BUYER 1), as the acquirer, is liable alongside the former owner for the real estate tax payable on the PURCHASE OBJECT for the period since the beginning of the last calendar year prior to the transfer of title. The aforementioned indemnification claims of BUYER 1) against the SELLER shall become due for payment five (5) BANKING DAYS after the liability claims of the tax office have fallen due, but not earlier than ten (10) BANKING DAYS after the determination of the respective liability notice by BUYER 1) to the SELLER. BUYER 1) shall be
obliged to notify the competent authority of the transfer of business pursuant to section 138 of the German Tax Code (AO) within one month after the TRANSFER DATE and to forward a copy of the notification to the SELLER without delay. The obligation of the SELLER to indemnify provided for in this Clause 4.8 shall only exist if and to the extent that a claim for liability of BUYER 1) can be asserted by the tax office despite timely notification by BUYER 1) pursuant to section 138 of the German Tax Code (AO) had been made.

4.9. BUYER 1) will inform the SELLER without delay about measures of the tax authorities which may lead to a claim against BUYER 1) for which the SELLER is liable on the basis of the agreements in this Contract (in particular input tax correction caused by the SELLER, liability according to section of the German Tax Code (AO)).

4.10. If a claim of BUYER 1) comes into consideration, because of which it can demand a compensation from the SELLER according to the above regulations, BUYER to 1) is obliged,
   a) immediately to forward to the SELLER the tax assessment on which the disadvantage is based,
   b) at the written request of the SELLER, but no later than five (5) BANKING DAYS before the expiry of the respective time limit for objection with respect to the relevant tax assessment, and at the SELLER’s expense, to lodge an appeal thereagainst, and
   c) to cooperate with the SELLER in the exercise of the remedies in order to avoid a claim against BUYER 1). If BUYER 1) culpably fails to comply with the aforementioned obligations, the corresponding indemnification obligation of the SELLER shall lapse, unless BUYER 1) proves that a claim against BUYER 1) could not have been avoided even in the event of dutiful conduct.

4.11. For the sale of PURCHASE OBJECT 2, section 13b of the German Value Added Tax Act (UStG) is not applicable. In this respect, according to sections 13a pars. 1 no. 1 of the German Value Added Tax Act (UStG), the SELLER is the debtor of the statutory VAT, which, however, must be borne by BUYER 2). The payment of the VAT to the SELLER by BUYER 2) shall be due as soon as the SELLER has issued a proper invoice within the meaning of section 14 of the German Value Added Tax Act (UStG). The list of items to be transferred subject to VAT is set out in Annex 2.2. Insofar as not all items to be transferred subject to VAT are included in Annex 2.2, the PARTIES hereby clarify that the foregoing shall also apply to all assets not included but to be transferred.

4.12. Claims of the PARTIES for exemption or refund of taxes under this Clause 4 shall expire at the earliest six months after the final substantive and formal validity of the underlying tax or liability assessment which gave rise to the claim of the respective PARTIES, but at the latest 48 months after transfer of ownership.
5. DEFAULT, PAYMENT AND DEFAULT

5.1. The PURCHASE PRICE (including any VAT) shall be paid no later than December 30, 2022 (receipt) into a notarial account of the acting notary named by the NOTARY (hereinafter referred to as the “NOTARIAL ACCOUNT”). In the event of default, the BUYERS shall pay interest on arrears at the statutory rate, without prejudice to further statutory claims. Payments shall be deemed to have been made only if they are made free of any conditions or only subject to such conditions of use as are not inconsistent with this Purchase Contract. The payer shall be bound by its fiduciary obligations in this respect for a period of at least four (4) months. In connection with section 8 of the Money Laundering Act (GwG), BUYER and SELLER declare that they are each acting on their own account.

Any positive interest as well as negative interest or custody fees during the deposit of the amount shall be due to the SELLER. As far as the deposited amount is subject to a negative interest or custody fees are to be paid for the NOTARIAL ACCOUNT, these are to be borne by the SELLER and to be deducted from the PURCHASE PRICE. The Notary is irrevocably instructed to inform the SELLER (with a copy to the BUYERS) of the resulting compensation amount with the NOTARY NOTIFICATION. With regard to the bearing of costs for the NOTARIAL ACCOUNT reference is made to Clause 17.2. The SELLER shall have the negative interest or custody charges—if possible with priority—advocated separately. In this case, it will invoice the corresponding amount separately to the SELLER.

The payment on the NOTARIAL ACCOUNT has no redemption effect on the SELLER's purchase price claim. The redemption effect is effected by the payment of the deposited amount by the NOTARY to the SELLER or, if applicable, to the creditor pursuant to an instruction in the escrow order yet to be issued in accordance with the following regulation.

5.2. The NOTARY is irrevocably authorized and instructed to pay the PURCHASE PRICE deposited on the NOTARIAL ACCOUNT upon the occurrence of the PAYMENT CONDITIONS with debt discharging effect to the account of the SELLER:

Bank: [***]
IBAN: [***]
BIC: [***]

5.3. In the event of rescissiion (see Clause 16) or non-execution of this Contract, the NOTARY is hereby unilaterally and irrevocably instructed by the PARTIES to pay the PURCHASE PRICE without delay to the BUYERS to accounts to be designated by them. The NOTARY shall, however, inform the SELLER in writing in advance of any payment; if the SELLER thereupon within ten (10) banking days asserts in writing to the SELLER—without a copy to the BUYERS—in a conclusive manner that the BUYERS are responsible for the rescission or the non-performance of this Contract, a joint instruction of the PARTIES or a fully executable court decision in this respect shall be required for the payment of the DEFERRED AMOUNT. After the last payment has been made, the acting NOTARY shall be authorized to settle the NOTARIAL ACCOUNT by sending a copy of the register of assets to the PARTIES.

The PARTIES have been informed that instructions deviating from and/or additional to those given above may only be given to the NOTARY by mutual agreement and in writing.

8
5.4. "DUE DATE CONDITIONS" are:

5.4.1. Not used.

5.4.2. The NOTARY has received the required waivers or negative certificates from the competent authorities regarding all statutory pre-emption rights as well as any required public or private law permits or declarations of consent in a form suitable for the Land Register, with the exception of the clearance certificate of the competent tax office with regard to the real estate transfer tax, the procurement of which lies exclusively within the legal sphere of the BUYER, as well as such approvals or declarations with regard to which BUYER 1) after request by the NOTARY or the competent authority, respectively, has not paid in due time the advance payment or the final fee, as the case may be, to the competent authority for the issuance or processing of the relevant permit; and

5.4.3. Not used.

The acting NOTARY is instructed to obtain the required permits or approvals, as required in Clauses 5.4.1 through 5.4.3.

Furthermore, the acting NOTARY is instructed to notify and confirm the existence of the prerequisites pursuant to Clauses 5.4.1 to 5.4.3 immediately as a pdf-copy by e-mail to the respective authorized representatives of the PARTIES in accordance with Clause 18.

5.5. The SELLER shall confirm to the NOTARY (with a copy to the BUYERS) by mail when the PURCHASE PRICE has been paid in full.

5.6. Offsetting and the assertion of rights of retention and rights to refuse performance against payment claims of the SELLER are excluded, unless the offsetting or rights of retention and rights to refuse performance are based on claims of the BUYERS against the SELLER which are undisputed, ready for decision or legally established.

6. TRANSFER OF OWNERSHIP, CHANGE OF USE AND ENCUMBRANCE, DEVELOPMENT

6.1. The transfer of the PURCHASE OBJECT to the BUYERS shall take place at the beginning of the first calendar day (00:00 hours) of the month following the month in which the full PURCHASE PRICE (including any interest accruing) is credited to the NOTARIAL ACCOUNT ("TRANSFER DATE"); it is clarified that the surrender of PURCHASE OBJECT 2 shall take place on the TRANSFER DATE with regard to the PROPERTY. The BUYERS are entitled and also obliged to take possession of the respective PURCHASE OBJECT directly on the TRANSFER DATE; the PARTIES waive a formal surrender.
6.2. Change of use and burden

6.2.1. On the TRANSFER DATE, the benefits and burdens, the risk of accidental deterioration and accidental loss as well as the obligations to ensure the safety of the PURCHASE OBJECT or to the PURCHASE OBJECT shall pass to the respective BUYER.

6.2.2. The BUYERS shall enter into the rights and obligations arising from the possession and ownership of the respective PURCHASE OBJECT in place of the SELLER as of the TRANSFER DATE. As of the TRANSFER DATE, the BUYERS shall indemnify the SELLER against all obligations arising from the possession and ownership of the respective PURCHASE OBJECT and their economic transfer to the respective SELLER. The obligations, burdens and costs shall be settled between the PARTIES pro rata temporis to the TRANSFER DATE, unless otherwise stipulated in this purchase contract.

6.2.3. Within one month after the TRANSFER DATE, the SELLER shall hand over to the BUYERS all documents available to it or to third parties commissioned by it. The SELLER is not obliged to procure documents which are neither available to him nor to third parties commissioned by it. If and as long as it needs them due to existing legal obligations or to enforce its own claims, the SELLER is entitled to keep copies or originals of these documents. If the SELLER retains originals, it shall provide the BUYERS with copies in advance.

6.3. Development

6.3.1. PURCHASE OBJECT 1 is sold in the state of development existing at the time of notarization. Development contributions pursuant to section 127 para. 1 of the German Building Code (BauGB), development levies pursuant to the relevant municipal levy laws or local bylaws, other levies and claims subject to contributions, as well as contributions by local residents, including claims for reimbursement of costs, and the corresponding costs for connections to the supply and disposal companies (in this Purchase Contract—together—referred to as “DEVELOPMENT COSTS”) shall be borne by the BUYER in deviation from section 436 of the German Civil Code (BGB) and irrespective of the contribution obligation under public law. The SELLER shall bear the costs of the fittings as far as they concern fittings already completed today, in all other respects BUYER 1 shall bear the costs of the fittings. As far as the SELLER has made advance payments on the aforementioned obligations and BUYER 1 receives a repayment in this respect, BUYER 1 is obliged to pay the corresponding amount to the SELLER without delay. BUYER 1 has to inform the SELLER about possible repayments in writing without delay.

Building cost subsidies, house connection costs and additional charges of development costs, which are requested on the occasion of a future development of PURCHASE OBJECT 1 or future changes of the development facilities, shall in any case affect BUYER 1 as far as they have not yet been paid.

6.3.2. The provisions in Clause 6.3.1 shall apply to any compensation amounts within the meaning of sections 154 et seq. of the German Building Code (BauGB), as well as to compensatory levies (e.g. for compensatory measures under nature conservation law in accordance with sections 155a of the German Building Code (BauGB) and other obligations under the relevant nature conservation and landscape laws (implementation of green measures, compensatory and/or replacement measures, etc.).
6.3.3. The PARTIES shall indemnify each other against any claim contradicting the above distribution in the internal relationship.

7. PERIOD BETWEEN NOTARIZATION AND TRANSFER DATE

7.1. For the period between today’s notarization and the TRANSFER DATE the SELLER is entitled and obliged:

7.1.1. to manage the PURCHASE OBJECT within the scope of due diligence in its own affairs (section 277 of the German Civil Code (BGB)). The SELLER shall carry out the maintenance prescribed for safety-relevant equipment—if not owed by the lessee—in accordance with the respective prescribed maintenance intervals. Maintenance and repair work, including replacements and replacements, however, shall only be carried out by the SELLER—if not owed by the lessee—to the extent necessary to prevent an imminent material deterioration of the PURCHASE OBJECT beyond normal wear and tear or age-related deterioration. The obligation to carry out such measures further presupposes that the measures do not relate to a circumstance (defect, damage, etc.) which was already known to the BUYERS or could have been known to them;

7.1.2. not to grant or apply for any encumbrances on PURCHASE OBJECT 1 and not to change or cancel any rights existing in favor of PURCHASE OBJECT 1 without the prior consent of BUYER 1), except as provided for in this Purchase Contract;

7.1.3. not to undertake any substantial alterations or other substantial structural measures or changes in the management of the property without the prior consent of BUYER 1), unless otherwise stipulated in this Purchase Contract or unless measures are required within the scope of the rental contract or public law obligations, in particular to avert dangers.

7.2. The SELLER remains entitled beyond the TRANSFER DATE to collect all claims to which it is entitled in connection with PURCHASE OBJECT 1 and, if necessary, to assert them in court.

8. PROPERTY CONTRACTS

Not used.

9. LEASEHOLD RELATIONSHIP AS LANDLORD

9.1. The PURCHASE OBJECT is leased. The BUYERS are aware of the lease agreement attached as a copy in Annex 9.1 including its addenda No. 1 and No. 2 (in short “LEASE AGREEMENT”). The BUYERS are also aware that the annexes to the Addenda No. 1 and No. 2 are not available.
9.2. The LEASE AGREEMENT is taken over by BUYER 1) with effect from the TRANSFER DATE. The SELLER and BUYER 1) are obligated to place each other in such a position as if the LEASE AGREEMENT taken over by BUYER 1) according to sentence 1 had been transferred in its entirety to BUYER 1) on the TRANSFER DATE.

9.3. The claims arising from the LEASE AGREEMENT (including subsequent entries) are assigned to BUYER 1) already today subject to a condition precedent and with effect as of the TRANSFER DATE. BUYER 1) accepts the assignment. The SELLER shall notify the lessee of the assignment in due time so that the lessee can transfer the payments to BUYER 1) in due time on the TRANSFER DATE. BUYER 1) is authorized to disclose the assignment to the lessee after the TRANSFER DATE. Income from advance rent payments shall be settled by the SELLER in proportion to the contracting parties on the TRANSFER DATE. Differences are to be settled immediately after determination. Changes or additions to the lease agreement (including termination) are to be made by the SELLER as of today’s date only with the consent of BUYER 1). The SELLER declares with regard to assigned claims and rights that it has no knowledge of them, that it is not the owner of them and that it has not encumbered them with rights of third parties or that any encumbrances due to the financing end with the TRANSFER DATE.

9.4. The SELLER will settle the service charges with the lessee for the settlement periods (calendar year) up to and including 2022. The statement of ancillary costs for 2022 vis-à-vis the lessee shall be prepared by the SELLER by December 31, 2023 (for 2022) and executed vis-à-vis the lessee, unless it has already been prepared. BUYER 1) shall, upon written request of the SELLER, immediately provide the SELLER with the documents required for the settlement of heating and operating costs, in particular accounting documents, which are available to the SELLER as of the date of delivery, insofar as and to the extent that the SELLER requires them for the settlement of the settlement period 2022; if and insofar as BUYER 1) does not provide the SELLER with the required information and documents, the SELLER shall carry out an interim settlement vis-à-vis BUYER 1) on the TRANSFER DATE and provide this to BUYER 1); the settlement for the settlement period 2023 shall then be the responsibility of the BUYER. The SELLER has to release BUYER 1) from claims of the lessee from all—to be settled by the SELLER—settlement periods (calendar year), which arise before the TRANSFER DATE, all claims against the lessee and payments of the lessee concerning these settlement periods are due to the SELLER until the TRANSFER DATE, from the TRANSFER DATE onwards to BUYER 1) and have to be paid to BUYER 1) or the SELLER respectively without delay, free of costs and charges in full to the SELLER or BUYER 1); BUYER 1) has no right of set-off or retention in this respect. Insofar as the ancillary cost statements for 2021 result in additional payments by the lessee which relate to the period up to the TRANSFER DATE, the SELLER shall be entitled to claim these from the lessee for its own account; it shall also satisfy any repayment claims of the lessee and indemnify BUYER 1) accordingly.
The settlement of accounts vis-à-vis the lessee for all future settlement periods (2023 et seq.) is—subject to subparagraph 1 a.E.—the responsibility of BUYER 1). The SELLER shall provide and account to BUYER 1) with all necessary documents available to it at the time of transfer of possession, otherwise immediately upon receipt, but not before the TRANSFER DATE in the original for the ancillary cost settlement in an orderly and auditable manner. Subject to subsection 1 a.E., no interim settlement shall be made to the lessee with reference to the date of the TRANSFER DATE. The SELLER shall provide BUYER 1) with a copy of the documents used for the 2021 settlement immediately after the TRANSFER DATE and with the original documents immediately after the settlement has been made.

9.5. It is clarified that the lessee has not provided rental security.

9.6. The SELLER hereby irrevocably authorizes and empowers BUYER 1) with effect from the TRANSFER DATE until the transfer of ownership of PURCHASE OBJECT 1 to make all legal declarations to the Lessee and, if necessary, to conduct the corresponding legal proceedings in its own name in a voluntary capacity, where the SELLER shall not be exposed to any risk of litigation or costs. The foregoing power of attorney may not be exercised in the internal relationship until the transfer of possession and thereafter only in such a way that neither the SELLER is obligated nor any claims remaining with the SELLER against the lessee are limited or cancelled. At the request of BUYER 1) the SELLER will issue corresponding written powers of attorney in separate documents in the number desired by BUYER 1).

9.7. The SELLER does not guarantee the tenancy or the creditworthiness of the lessee, unless otherwise agreed in this Deed. The SELLER declares, however, that on the day of the notarization, to its knowledge

9.7.1. the original copy of the LEASE AGREEMENT attached hereto as Annex 9.1 (with regard to Addendum No. 1 and No. 2, however, without Annexes) is available and no further lease and tenancy agreements exist with regard to PURCHASE OBJECT 1 which are transferred to BUYER 1) pursuant to sections 566 et seq. of the German Civil Code (BGB);

9.7.2. there are no advance rent claims and/or claims for rent and/or ancillary costs as of the TRANSFER DATE;

9.7.3. the LEASE AGREEMENT attached hereto as Annex 9.1 has not been terminated (i.e. no notices of termination have been given to the SELLER by the lessee nor has the SELLER given notice of termination to the lessee) or has not been terminated by mutual consent or such termination has not been threatened in writing to the SELLER within the last three (3) months prior to the date of the notarization (also not with effect for a date in the future);

9.7.4. rental securities have not been agreed;

9.7.5. there are no unresolved rent reductions;

9.7.6. no legal disputes with the tenant are pending or threatened in writing;

9.7.7. the lessee has not requested cancellation or termination of the lease.

9.8. The SELLER shall indemnify BUYER 1) against all rights and claims of the lessee which become due from the date of delivery and which relate to the period from the date of delivery, unless otherwise agreed below.
10. LEASEHOLD RELATIONSHIP AS LESSEE

10.1. The SELLER, as lessee, has entered into the lease agreement with third parties for traffic areas ("LEASE-IN AGREEMENT") as set forth in Annex 10.1, a copy of which is attached hereto.

10.2. BUYER 1) takes over the LEASE-IN AGREEMENT with effect from the TRANSFER DATE as lessee.

10.3. BUYER 1) shall—subject to the consent of the contracting party—assume all rights and obligations under the LEASE-IN AGREEMENT (assumption of the agreement) as of the date of transfer and shall release the SELLER from all rights and claims of the contracting party in connection therewith as of the TRANSFER DATE and insofar as they relate to the period after the TRANSFER DATE. The SELLER shall inform the other party to the agreement immediately after the TRANSFER DATE about the (intended) assumption of the agreement and obtain the other party’s consent to the assumption of the agreement by BUYER 1) as of the TRANSFER DATE, which shall release the SELLER from its obligations. BUYER 1) is obliged to support the SELLER in the transfer of the LEASE-IN AGREEMENT to BUYER 1)—in particular towards the contracting party—and in particular to sign the agreement on the debt-discharging takeover of the agreement.

Furthermore, the SELLER undertakes, as of today’s notarization, to cancel, terminate or change the LEASE-IN AGREEMENT (to be continued by BUYER 1) only with the consent of BUYER 1).

10.4. If the consent of the other party to the agreement required for the assumption of the agreement is not granted, the SELLER and BUYER 1) shall be obliged to place themselves in the same position in the internal relationship as if the LEASE-IN AGREEMENT had also been transferred to BUYER 1) in the relationship of succession on the TRANSFER DATE (assumption of performance). For this purpose, the SELLER shall assign to BUYER 1) all claims and rights arising from or in connection with the LEASE-IN AGREEMENT with effect from the TRANSFER DATE and the SELLER shall terminate the LEASE-IN AGREEMENT—if possible—after prior consultation with BUYER 1) at the earliest possible date, which may not be later than the TRANSFER DATE. From the TRANSFER DATE until, if applicable, the termination of the LEASE-IN AGREEMENT, the SELLER shall continue the LEASE-IN AGREEMENT for the account and at the expense of BUYER 1), who shall indemnify the SELLER in accordance with this Clause 10.3, or, as far as possible, BUYER (1) shall perform its obligations under the LEASE-IN AGREEMENT itself (assumption of performance).
11. INSURANCES
The existing building property and liability insurances will be continued by the SELLER at its own expense until the TRANSFER DATE. These insurance contracts cannot be taken over by BUYER 1) in deviation from section 95 of the German Insurance Contract Act (VVG) and will be terminated by the SELLER with effect from the TRANSFER DATE at its own expense and instigation. BUYER 1) therefore undertakes to insure PURCHASE OBJECT 1) at its own expense to the appropriate reasonable extent as of the TRANSFER DATE and to maintain insurance coverage with sufficient coverage until the transfer or transfer of title in the Land Register of the property and to prove this to the SELLER immediately upon request.

12. ASSIGNMENT OF CLAIMS

12.1. The SELLER hereby assigns to BUYER 1), subject to a condition precedent of the TRANSFER DATE, any claims for removal of defects of BUYER 1) still due to it from construction work on PURCHASE OBJECT 1) and undertakes, to transfer to BUYER 1) any securities and contractual documents existing in this respect and still available to SELLER within one (1) month after the TRANSFER DATE, unless already in the (indirect) possession of BUYER 1). An overview of the securities is attached hereto as Annex 12.1.

The assignment shall be conditional upon the rescission of this Contract or its other rescission or non-performance. The SELLER shall not be liable for the existence, assignability and/or enforceability of any claims and rights arising from contracts to be assumed by BUYER 1) under this PURCHASE CONTRACT and/or of any claims or rights which BUYER 1) otherwise has under this Contract and/or which are assigned to it. Nevertheless, the SELLER declares that it has no knowledge of circumstances which could affect the existence, assignability and enforceability of these claims and rights.

The SELLER shall no longer be entitled to collect claims assigned under this PURCHASE CONTRACT, except for any claims assigned by way of security, as of the date of sale. However, insofar as the SELLER is liable to BUYER 1) for circumstances covered by the assignment in accordance with the provisions of this Purchase Contract, BUYER 1) hereby assigns the corresponding claims against third parties back to the SELLER accepting this, subject to the condition precedent that the claims asserted by BUYER 1) against the SELLER are fulfilled by the SELLER.

The foregoing shall apply mutatis mutandis to claims arising from and/or in connection with PURCHASE OBJECT 2.

12.2. Insofar as the SELLER is entitled to assignable rights of use and exploitation under copyright law with regard to the PURCHASE OBJECT, the SELLER shall assign such rights to BUYER 1) accepting this assignment subject to a condition precedent and with effect from the TRANSFER DATE. BUYER 1) shall indemnify the SELLER against any rights and claims of third parties in connection with any existing copyrights.
13. GUARANTEE / LIABILITY OF THE SELLER / ENVIRONMENTAL CONTAMINATION

13.1. Unless otherwise expressly agreed in this Purchase Contract, the PURCHASE OBJECT is sold in its present condition, as it stands and is situated, to the exclusion of all liability for defects of title and quality. This Purchase Contract governs the liability of the SELLER conclusively. Any rights of the BUYER not provided for in this Purchase Contract, in particular any statutory claims for performance, guarantee, expenses, reimbursement and/or damages, whether based on pre-contractual breach of duty (culpa in contrahendo), rescission, breach of contract or tort, are excluded.

Contractual disputes arising from the purchase of movable property do not affect the property purchase agreement; the agreements are independent of each other in this respect. The condition of the PURCHASE OBJECT due to use is known to the BUYERS.

13.2. The SELLER shall not be liable for any economic or actual deterioration of the PURCHASE OBJECT occurring from the date of the notarization of this Purchase Contract until the TRANSFER DATE which is merely normal wear and tear, or which occurs due to age or which was foreseeable. The SELLER shall be liable for any further deterioration of the PURCHASE OBJECT occurring up to the TRANSFER DATE only to the extent that the SELLER has caused such deterioration intentionally or by gross negligence. If the deterioration represents an insured event, the BUYERS are in each case entitled, subject to the TRANSFER DATE, to demand the surrender of the insurance benefit from the SELLER, in the case of liability of the SELLER, however, only instead of the removal of the deterioration or compensation for the damage by the SELLER. Other rights and claims of the BUYER due to possible deterioration of the PURCHASE OBJECT are excluded.

13.3. Subject to the provision in Clause 13.5, the SELLER declares to BUYER 1) in the form of an independent guarantee undertaking pursuant to section 311(1) of the German Civil Code (BGB), that the statements in Clause 13.4 (hereinafter referred to as “SALE GUARANTEES”) are correct on the date of signing of this Purchase Contract (hereinafter referred to as the “SIGNING DATE”), unless otherwise disclosed to BUYER 1). Declarations of knowledge of the SELLER refer in each case to the point in time five BANKING DAYS before the date of signing. The PARTIES agree that the SELLER does not warrant the condition of any item within the meaning of section 443 of the German Civil Code (BGB) and represents no guarantee of quality pursuant to sections 434(1) of the German Civil Code (BGB). For this reason, the PARTIES also agree that section 444 of the German Civil Code (BGB) does not apply to any of the sales guarantees.

13.4. Sales guarantees

13.4.1. The SELLER is the owner of the REAL PROPERTY sold by it.

13.4.2. The SELLER has not applied for or approved any changes to the contents of the Land Register listed in Clause 1, has not submitted any applications for entry in the register of building encumbrances and has not issued any declarations of commitment to enter building encumbrances.
13.4.3. The SELLER is not aware of any easements under prior law on the REAL PROPERTY sold by it.

13.4.4. The SELLER has not entered into any neighborhood covenants or urban development covenants with respect to PURCHASE OBJECT 1.

13.4.5. To the SELLER’s knowledge, there are no unfulfilled ordinary orders or requirements for PURCHASE OBJECT 1 and its uses.

13.4.6. To the SELLER’s knowledge, there are no legal disputes or administrative appeal proceedings pending with respect to PURCHASE OBJECT 1 to which the SELLER is a party.

13.4.7. The SELLER has not entered into any employment contracts with respect to PURCHASE OBJECT 1 sold by it, nor has it engaged any “freelance” employees in this respect, who are to be transferred to the BUYERS by the execution of this Purchase Contract pursuant to section 613a of the German Civil Code (BGB).

13.5. Claims and rights in the event of breach of sales guarantees

13.5.1. The BUYERS shall grant the SELLER a reasonable period of time, but not less than 20 (twenty) BANKING DAYS, to restore the contractual condition of the PURCHASE OBJECT. After the expiry of this period, the SELLER shall be obliged to pay damages in money to the BUYERS in accordance with the following provisions of sections 249 et seq. of the German Civil Code (BGB). Claims of the BUYER for the establishment of the contractual condition are then excluded.

13.5.2. Claims and rights of the BUYERS are excluded if and to the extent that the possible damage can be met or compensated by a third party (in particular an insurance company).

13.5.3. The SELLER shall not be liable with respect to sold and/or assigned rights and claims, neither for their existence nor for their assignability, enforceability or value.

13.6. All claims and rights of the BUYERS arising from and in connection with this Purchase Contract, in particular also due to any material defects and defects of title, shall expire after the expiry of eighteen (18) months from the TRANSFER DATE. The claim of BUYER 1) for the transfer of title shall expire, notwithstanding the foregoing, after ten years from the date of transfer.
13.7. All disclaimers and limitations of liability contained in this purchase agreement shall not apply to any liability
13.7.1. for damages resulting from injury to life, body or health, if the SELLER is responsible for the breach of duty,
13.7.2. for other damages which are based on a deliberate or grossly negligent breach of duty by the SELLER and
13.7.3. due to intentional or fraudulent concealment of defects.

13.8. Environmental Contamination

13.8.1. “ENVIRONMENTAL CONTAMINATION” in the sense of this Purchase Contract are contaminations, waste,
decommissioned facilities and hazardous substances. “POLLUTANTS” within the meaning of this Purchase Contract are, in accordance with the German Federal Soil Protection Act (BBodSchG), concentrations of pollutants or substances to be eliminated for use-related remediation (see section 4(4) of the German Federal Soil Protection Act (BBodSchG)) to be eliminated are concentrations of pollutants or deposits in the soil, soil air, buildings and groundwater, seepage water and surface water which may impair the use of the property or change the quality of the groundwater, as well as contaminated sites and harmful soil changes within the meaning of the German Federal Soil Protection Act (BBodSchG). “WASTE” within the meaning of this Purchase Contract shall be items, substances and materials which are to be disposed of, disposed of, recycled or otherwise treated in accordance with waste management regulations. “STORAGE FACILITIES” means tanks, underground pipes, underground conduits and other underground facilities which are not required for the operation of the property. “HAZARDOUS MATERIALS” for purposes of this Purchase Contract means hazardous construction and other materials (including, without limitation, asbestos, lead-containing or radioactive materials, formaldehyde, polychlorinated biphenyls (PCBs), polycyclic aromatic hydrocarbons (PAHs), ozone depleting substances, and artificial mineral fibers) and unexploded munitions, ordnance and other explosives and other remnants or parts thereof.

13.8.2. The SELLER shall not be liable for the freedom of PURCHASE OBJECT 1 from ENVIRONMENTAL CONTAMINATION, unless the SELLER is responsible for such ENVIRONMENTAL CONTAMINATION or unless otherwise provided hereinafter. Any liability of the SELLER resulting from an ENVIRONMENTAL CONTAMINATION on PURCHASE OBJECT 1, irrespective of its origin, its extent or its legal basis, shall be expressly excluded, in particular any liability arising from pre-contractual breach of duty (section 311(2) and section 311(3) of the German Civil Code (BGB)), breaches of duty arising from the obligation as well as from unauthorized action, unless the SELLER is responsible for such an ENVIRONMENTAL CONTAMINATION or insofar as nothing to the contrary is stipulated below.

Insofar as the SELLER is held liable under public and/or private law for ENVIRONMENTAL CONTAMINATION, although its liability towards BUYER 1) is excluded under this Contract, BUYER 1) shall indemnify the SELLER against this claim and the resulting burdens, in particular obligations, costs, expenses and/or damages. The indemnification as well as the waiver of any compensation claims shall also apply in favor of such persons or companies who are liable for a responsibility of the SELLER due to ENVIRONMENTAL CONTAMINATION, in such a way that these persons or companies are directly entitled from this provision.
Insofar as BUYER 1) is held liable under public and/or private law for ENVIRONMENTAL CONTAMINATION, although the SELLER is liable for this under this Contract, the SELLER shall indemnify it against this claim and the resulting burdens, in particular obligations, costs, expenses and/or damages. The indemnification as well as the waiver of any compensation claims shall also apply in favor of such persons or companies who are liable for a responsibility of BUYER 1) due to ENVIRONMENTAL CONTAMINATION, in such a way that these persons or companies are directly entitled from this provision.

Claims under section 24(2) of the German Federal Soil Protection Act (BBodSchG) and/or section 9(2) of the Law on the Prevention and Remediation of Environmental Damage (USchadG) are expressly excluded insofar as they either economically or legally contradict or circumvent the above provisions. This obligation shall also apply in the event that compensation claims are asserted by third parties, such as subsequent purchasers, against the SELLER or BUYER 1). BUYER 1) shall not assert any claim for compensation pursuant to section 24(2) of the German Federal Soil Protection Act (BBodSchG) or for joint and several compensation in connection with an acceptance of a claim pursuant to sections 89, 90, 22 of the Law on the Order of the Water Balance (WHG) or pursuant to section 9(2) Law on the Prevention and Remediation of Environmental Damage (USchadG) or any other claims for compensation based on similar public law provisions (collectively the “COMPENSATION CLAIM”). The Parties each accept this waiver.

13.8.3. Notwithstanding the foregoing liability provision for ENVIRONMENTAL CONTAMINATION, the PARTIES agree as follows with respect to the costs associated with the removal of ENVIRONMENTAL CONTAMINATION on PURCHASE OBJECT 1:

a) In the event of any ENVIRONMENTAL CONTAMINATION on PURCHASE OBJECT 1, which can be proven to have their cause in a circumstance that occurred in the period between the transfer of ownership to the SELLER and June 1, 2014, the SELLER shall participate in the CONTAMINATION-RELATED ADDITIONAL EXPENDITURE resulting from the removal of the ENVIRONMENTAL CONTAMINATION up to the amount of EUR [***] plus the respective statutory value-added tax (“THRESHOLD VALUE”); the additional costs for the CONTAMINATION-RELATED ADDITIONAL EXPENDITURE shall be borne by BUYER 1).
b) The costs to be borne by the SELLER for CONTAMINATION-RELATED ADDITIONAL EXPENDITURE until the SELLER reaches the THRESHOLD VALUE are defined as follows:
   
   (i) Disposal costs (transport and landfill costs; transport and disposal to an officially licensed disposal center incl. charges, organization [EVN, consignment bill, etc.], tipping fees and containers) for
      
      (aa) Excavated material with a LAGA classification value ≥ (greater/equal) LAGA Z 2
      (bb) Building material with an allocation value ≥ (greater/equal) RW 2
      (cc) other contamination inherent to the building material (e.g. asbestos, CMF) and/or concrete contamination (e.g. oil or PCB, etc.)
(ii) less any disposal/separation costs for material with a charge lower than that specified in (i) (aa) to (cc);

(iii) plus half the costs of the expert accompanying the measures, including the costs of laboratory analysis.

c) The following shall be excluded from the SELLER’s liability for the cost of CONTAMINATION-RELATED ADDITIONAL EXPENDITURE in the aforementioned sense

(i) all excavated material with a load according to (b) (i) (aa) above below the top/flat of the terrain as well as

(ii) all building material and/or technical installations and parts thereof with a load as per (b) (i) (bb) and (cc) above in structural installations below the bare concrete floor of the first floor, as well as loads as per (b) (i) (aa) to (cc) above on structural and technical installations and parts thereof enclosed in the ground.

d) The cost absorption by the SELLER according to paras (a) to (c) requires that the following procedure is observed by BUYER 1):

BUYER 1) shall comprehensively involve the SELLER or the third party designated by it within the scope of the investigation of PURCHASE OBJECT 1, then within the scope of an individual tender to be carried out for the decontamination and disposal services and the engineering services as well as in the execution of the decontamination and disposal services and shall create a transparent procedure.

The SELLER or the third party appointed by it shall be involved in the procedure; in particular, it shall be entitled to participate in all award negotiations, etc. The SELLER shall be informed of the award documents received and their evaluation. The tender documents, the bids received and their evaluation, award protocols, etc. shall be disclosed to him. In the case of a restricted tender, both PARTIES shall agree on the list of bidders. The invocations to tender shall be made on the basis of a performance specification with detailed disposal items (in particular breakdown according to LAGA category values) and subdivided engineering services. The SELLER shall be informed comprehensively about the unit prices achieved for the individual items of the CONTAMINATION-RELATED ADDITIONAL EXPENDITURE during the awarding of the contract. The SELLER shall be entitled, if in its opinion these individual items do not correspond to the usual prices, to enquire about companies selected on the basis of the short tender. Based on the results obtained hereon, the PARTIES will agree on the unit prices for the CONTAMINATION-RELATED ADDITIONAL EXPENSES.

BUYER 1) must assert his claims for cost sharing in writing and by submitting to the SELLER precise invoices and proof of disposal (including weighing bills, receipts for tipping fees, etc.). In doing so, he must also provide appropriate proof of the deduction of the disposal costs.
Claims for cost sharing are due for payment within eight (8) weeks after submission of a final report by the expert appointed by BUYER 1). The SELLER’s rights of retention and refusal of performance are excluded, unless no agreement on the unit prices (cf. above) has yet been reached.

The SELLER’s obligation to share the costs shall end with respect to PURCHASE OBJECT 1 four (4) years after the TRANSFER DATE. The date of receipt by the SELLER of the claim for cost sharing pursuant to subparagraph 4 above shall be decisive.

13.8.4. BUYER 1) is obligated—without giving up its own obligation to indemnify and without prejudice to the other provisions in this clause—in the event of a full or partial transfer or other transfer of BUYER 1) to impose the obligations set forth in Clause 13.8 to the respective subsequent owner in such a way that the SELLER is entitled to a direct claim against the respective subsequent owner and the agreed exclusions of liability, in particular with regard to § 24(2) of the German Federal Soil Protection Act (BlödschG), sections 22, 89, 90 of the Law on the Order of the Water Balance (WHG) and § 9(2) of the Law on the Prevention and Remediation of Environmental Damage (UStSchG) or other claims for compensation based on similar provisions of public law, shall also apply in the relationship between the third party purchaser and the SELLER.

Furthermore, the SELLER shall ensure by including appropriate provisions that the obligations set forth in this Clause 13.8 shall be imposed on subsequent owners in each further case of sale or each further other assignment. The obligations under Clause 13.8 shall be assumed by the respective successors in title as a true contract in favor of the SELLER as a third party. BUYER 1) is obligated, in the case of the conclusion of a purchase or other transfer contract with a third-party purchaser, to immediately provide the SELLER with a certified excerpt from the corresponding purchase contract, from which the fulfillment of the above obligation is evident.

The above claim for damages and the obligation to indemnify as well as the waiver and exclusion of any COMPENSATION CLAIM shall also apply directly (section 328 of the German Civil Code (BGB)) in favor of such persons who are liable for a responsibility of the SELLER or BUYER 1) due to ENVIRONMENTAL CONTAMINATION on the basis of commercial or corporate law. The respective persons are directly entitled from this Contract. The limitation period for claims for indemnification/compensation shall commence at the earliest when the persons entitled under the above provision make a claim.

13.8.5. The above regulations apply accordingly in the case of the presence of archaeological monuments.

13.8.6. According to the information of the City of Mainz dated December 19, 2022, PURCHASE OBJECT 1 is not listed as a suspected contaminated site. This information is known to the SELLER and BUYER 1) and is attached as Annex 13.8.6.
14. **CREATION OF LIENS ON REAL PROPERTY**
Not used.

15. **PRIOR NOTICE OF CONVEYANCE AND CONVEYANCE, TRANSFER OF TITLE**

15.1. **Notice of conveyance**

The registration of a priority notice of conveyance to secure the claim of BUYER 1) to transfer of ownership of PURCHASE OBJECT 1 pursuant to section 883 of the German Civil Code (BGB) is expressly waived in spite of the instruction of the NOTARY as to the risks involved.

15.2. **Conveyance**

15.2.1. The PARTIES wish to have the conveyance notarized and declare:

The SELLER and BUYER 1) unconditionally agree that the ownership of PURCHASE OBJECT 1) shall pass to BUYER 1).

15.2.2. The above declaration of conveyance does not contain any authorization of the SELLER to transfer the title. The SELLER hereby unilaterally irrevocably authorizes the NOTARY to separately declare such authorization. The PARTIES hereby unilaterally irrevocably instruct the NOTARY to approve the transfer of title, notwithstanding any other instructions in this Purchase Contract, and to apply for such transfer at the Land Registry pursuant to section 15 of the German Land Register Code (GBO), in any case only after (i) the SELLER has confirmed in writing the full payment of the PURCHASE PRICE or such payment is to be made by the BUYER, and (ii) the SELLER has confirmed in writing the full payment of the PURCHASE PRICE or such payment is to be made by BUYER 1) has been proven by bank confirmation. The PARTIES hereby unilaterally irrevocably waive the exercise of the application rights to which they are entitled with regard to the transfer of ownership.

15.3. The PARTIES agree on the transfer of ownership of PURCHASE OBJECT 2 subject to the receipt of PURCHASE PRICE 2. The ownership of PURCHASE OBJECT 2 shall pass to BUYER 2) upon payment of PURCHASE PRICE 2 to the account of the SELLER under Clause 5.2.

15.4. **WITHDRAWAL RIGHTS**

16.1. **Non-occurrence of the due date conditions**

Both PARTIES shall have the right to rescind this Purchase Agreement if the DUE DATE CONDITIONS have not occurred by December 31, 2023.

16.2. **Exercise of rights of first refusal**

22
16.2.1. Should a right of first refusal be exercised with respect to PURCHASE OBJECT 1, the SELLER shall be entitled to rescind this purchase contract with respect to the entire PURCHASE OBJECT.

16.2.2. Claims for damages or reimbursement of expenses of the BUYER against the SELLER are excluded in such a case.

16.2.3. If a right of first refusal is exercised only with respect to an insignificant part of PURCHASE PRICE 1, BUYER 1) — provided that the SELLER does not rescind pursuant to Clause 16.2.1 — shall continue to be obligated to pay the entire PURCHASE PRICE 1 in accordance with the provisions of this Contract. In return, the SELLER assigns to BUYER 1) the claims against the preemptor for payment of the PURCHASE PRICE or the statutory compensation. To the extent of the exercise of the right of first refusal, the SELLER shall be released from its performance obligations vis-à-vis BUYER 1); likewise, with regard to this part of PURCHASE OBJECT 1, the due date requirement pursuant to Clause 5.4.2 (Negative Acknowledgement/Declaration of Waiver) shall not apply. Further claims, in particular a right of withdrawal as well as claims for damages or reimbursement of expenses of BUYER 1) against the SELLER, are excluded in such a case.

16.2.4. If a right of first refusal is exercised or an official approval is refused or granted subject to a condition, the notice shall be served on the PARTIES themselves. Neither the NOTARY nor his notarial employees are authorized to receive the notice.

16.3. Default of payment

If the BUYERS default on payment of the PURCHASE PRICE in whole or in part for more than ten (10) BANKING DAYS after receipt of a reminder, the SELLER may rescind this Purchase Contract.

16.4. Lack of ownership

In case of breach of guarantee according to Clause 13.4.1, the SELLER shall be entitled to rescind the Purchase Contract in addition to the claims provided for in Clause 13.5.1.

16.5. Real estate transfer tax

16.5.1. If the SELLER is required by the Tax Office to make payment of the real estate transfer tax on the basis of this Purchase Contract and BUYER 1) does not pay the real estate transfer tax within ten (10) BANKING DAYS or does not provide adequate security within this period, the SELLER shall be entitled to rescind this Purchase Contract.

16.5.2. The aforementioned period shall commence after the SELLER has notified BUYER (1) in writing (sufficiently by fax) of the claim by the Tax Office.
16.6. General regulations concerning rescission

16.6.1. The rescission is to be expressed in writing to the NOTARY. The PARTIES hereby unilaterally irrevocably authorize the NOTARY to receive the declarations of rescission. The rescission shall become effective upon receipt of the declaration of rescission by the NOTARY. The NOTARY is obliged to send a copy of a declaration of rescission of one PARTY to the other PARTY immediately after receipt.

16.6.2. The right of rescission is excluded for the PARTY which is responsible for the reason for rescission.

16.6.3. The right of rescission shall expire as soon as the reason for rescission has completely ceased to exist before one of the PARTIES has effectively declared rescission.

16.6.4. The reimbursement of any purchase price payments made shall be made concurrently with the cancellation of the priority notice of conveyance in favor of BUYER 1) and any financing liens of BUYER 1) or, if the transfer has already taken place, BUYER 1) shall only be entitled to the return conveyance with such encumbrances as are to be assumed by BUYER 1) under this Purchase Contract. If the transfer has already taken place, BUYER 1) shall be obliged to transfer the property only with such encumbrances which were to be assumed by the BUYER to 1) according to this Purchase Contract and under cancellation of the financing liens of BUYER 1), concurrently against repayment of the PURCHASE PRICE already paid. The consequences of rescission shall be determined in accordance with sections 346 et seq. of the German Civil Code (BGB).

16.6.5. Claims for damages shall remain unaffected in the event that one of the PARTIES is at fault, according to the terms of this Purchase Contract.

16.6.6. Recission must be exercised within one (1) month from the date of knowledge of the occurrence of the respective right of rescission.

16.6.7. The costs, taxes or other expenses already incurred in the event of a rescission or still to be incurred as a result of the rescission, including the notary and deletion costs as well as the costs incurred in connection with the decision to purchase and sell, including any costs for the preparation of any necessary expert opinions, shall be borne by the contracting party giving rise to the rescission; in the event of rescission as a result of the exercise of a right of first refusal or for any other reason for which neither party is responsible, the SELLER and the BUYERS shall each bear their own costs for technical, legal and tax or other advisors, while the costs of this Contract shall be borne equally by the BUYERS and the SELLER.

16.6.8. Regardless of the legal basis, a rescission of this Purchase Contract can only be executed uniformly with regard to the entire PURCHASE OBJECT.
17. COSTS AND REAL ESTATE TAX

17.1. The notary and court costs for the notarization and execution of this Purchase Contract as well as the real estate transfer tax shall be borne by BUYER 1). However, the costs for the cancellation of such encumbrances which are not taken over by BUYER 1) after the issuance of this Purchase Contract shall be borne by the SELLER.

17.2. The costs for the cancellation of the NOTARIAL ACCOUNT at the NOTARY and at the BANK, also insofar as they are caused by payments for the redemption of any encumbrances, shall be borne by the SELLER; if necessary, they may be taken from the NOTARIAL ACCOUNT. The deposited amount is to be deposited as a deposit with the account-keeping credit institution. The SELLER shall be entitled to any interest credited, minus the interest income tax, and shall be paid out upon closure of the NOTARIAL ACCOUNT.

17.3. Each PARTY bears the costs of the consultants commissioned by it.

18. COMMUNICATIONS AND DECLARATIONS

18.1. All notices and declarations to be given in connection with the execution or performance of this Purchase Contract vis-à-vis the SELLER or BUYER 1) shall be made in German and, unless otherwise expressly agreed, shall be addressed in writing or any other form of transmission previously accepted by the relevant PARTY to the domestic receiving agents of the relevant PARTY at the domestic address last given by the relevant PARTY. The receiving agents designated by the PARTIES are—until a notice of change in accordance with Clause 18.2—:

18.1.1 for the SELLER:
Santo Service GmbH
v.d. ATHOS KG
[***]
Rosenheimer Platz 6
81669 Munich
eMail: [***]
with copy (pdf) to
(not a condition of effectiveness for the declaration)
[***]

18.1.2 for BUYER 1):
BioNTech Real Estate Ander Goldgrube 12 GmbH & Co. KG
[***]
Bergfeldstrasse 9
83607 Holzkirchen
eMail: [***]

25
18.1.3 for BUYER 2:

BioNTech Real Estate An der Goldgrube 12 GmbH & Co. KG
An der Goldgrube 12
55131 Mainz
E-mail: [***]

18.2. Until the appointment of a new domestic contact person and the provision of his full contact details in accordance with the requirements set out in Clause 18.1, the contact person most recently notified to the other PARTIES shall be deemed (unilaterally) irrevocably to be the receiving and service agent of the relevant PARTY.

19. CONTRACT EXECUTION

19.1. The NOTARY is appointed and authorized to execute and perform this Deed. The NOTARY shall obtain all official approvals and declarations; subject to Clause 16.2.4, these shall become effective vis-à-vis all PARTIES upon receipt by the NOTARY; he shall be exempt from the restrictions of section 181 of the German Civil Code (BGB) in this respect.

19.2. All Land Register applications contained in this Deed may also be made and withdrawn separately by the NOTARY.
19.3. The PARTIES authorize each for itself and its legal successors, under exclusion of personal liability, the notarial employees

- [***]
- [***]
- [***]

each with business address at [***], each individually, with exemption from the provisions of section 181 of the German Civil Code (BGB) and with the right to grant sub-authorization, to make and accept all declarations which may still be necessary or useful for the amendment, supplementation or enforcement or execution of this Purchase Contract, in particular vis-à-vis the Land Registry.

The authorized representatives are in particular authorized to declare or repeat the conveyance, to make declarations of identity and to approve and apply for entries in the Land Registry. All declarations of the authorized persons are only effective if they are made in a notarial record or certified by the NOTARY. The power of attorney also extends to the issuance of deletion declarations, corrections to this Purchase Contract, declarations of priority and the withdrawal of applications. The power of attorney is unrestricted vis-à-vis the Land Registry.

19.4. The powers of attorney shall take effect immediately, irrespective of the existence of any official approvals or other obstacles to the effectiveness of this Purchase Contract. The powers of attorney shall expire four weeks after the complete execution and execution of this Purchase Contract.

19.5. In the event of full or partial settlement or non-execution of this Purchase Contract, the power of attorney shall also entitle the parties to cancel any liens on real property which may have been created in accordance with Clause 14. The authorized representatives are hereby unilaterally irrevocably instructed by the PARTIES to make use of their power of attorney in such cases only after the delivery of this Purchase Contract.

20. TEACHINGS AND NOTES

The NOTARY instructed those present that

- the BUYER 1) acquires ownership of the PURCHASE OBJECT only with the transfer in the Land Register,
- for the transfer of ownership, among other things, the certificate of no objection to real estate transfer tax must be available and the court costs must be paid,
- the PARTIES are legally jointly and severally liable to the Tax Office for the real estate transfer tax as well as for notary’s and court costs on a pro rata basis,
- any agreements made within the framework of this document may lead to the nullity of the entire contract.

27
21. CONFIDENTIALITY

21.1. The PARTIES shall treat the conclusion and the contents of this Purchase Contract, including all attachments, the amount of the PURCHASE PRICE and all information/knowledge received in connection with the preparation and/or conclusion of this Purchase Contract as strictly confidential and shall maintain secrecy with respect thereto vis-à-vis third parties. This shall not apply, however, to companies affiliated with the PARTIES and to the consultants of the PARTIES, insofar as these are subject to secrecy by law or on the basis of existing provisions of company agreements.

21.2. Press releases and information to third parties concerning this transaction require in any case a prior mutual written agreement and consent between the PARTIES. This also applies in particular to the advisors accompanying the transaction and other parties involved.

21.3. However, mandatory statutory duties of disclosure and information are reserved and remain unaffected.

22. OTHER

22.1. After reviewing the relevant prerequisites, the PARTIES declare that the conclusion and the execution of this Purchase Contract are not subject to notification, approval or clearance under anti-trust law. They declare that, in addition, the relevant threshold value for the relevant turnover in the relevant period within the relevant radius for the PURCHASE OBJECT has not been reached or will not be reached.

22.2. Banking Days within the meaning of this Purchase Contract shall be all days on which commercial banks in Munich are generally open for business (“BANKING DAYS”)

22.3. For the purposes of this Deed, “NOTARY” means both the undersigned NOTARY and his successor in office, his officially appointed representative(s), and any other NOTARY associated with him in the practice of his profession.

22.4. The assumption of rights or obligations or contractual relationships or the entry into rights or obligations or contractual relationships by BUYER 1) in place of the SELLER in the course of this Purchase Contract shall—unless otherwise expressly agreed—in each case take place subject to a condition precedent on and with effect from the TRANSFER DELIVERY. The same shall apply insofar as the SELLER transfers movable goods to BUYER 1) within the scope of this Purchase Contract, assigns claims or transfers rights or securities or the rights and claims relating thereto. The assignment of rights and claims is also conditional upon the cancellation of this purchase contract or its cancellation or non-execution for any other reason, unless otherwise expressly stipulated in this Purchase Contract.

22.5. The place of jurisdiction for all disputes arising from or in connection with this Purchase Contract shall be Mainz, Germany, to the extent permissible.
22.6. If any provision of this Purchase Contract is or becomes invalid or unenforceable in whole or in part, this shall not affect the validity and enforceability of all other provisions of this Purchase Contract.

22.7. Unless the law prescribes a stricter form, changes to this Purchase Contract must be made in writing. This also applies to changes to this provision.

22.8. Should any provision of this Purchase Contract be or become invalid, voidable and/or unenforceable in whole or in part, this shall not affect the validity of the remaining provisions of the contract. The invalid / void / unenforceable provisions shall be replaced by an agreement that comes closest to the economic intent in a legally permissible manner. The same applies to any loosening of the Purchase Contract.

22.9. Of this Deed received:
   Certified copy:
   • the Land Registry
   Electronic copies:
   • each PARTY one
   Simple copies:
   • the Real Transfer Tax Office
   • the Municipality
   • the Surveyor’s Report
   PDF copies:
   • [***]
   • [***]

22.10. In detail, the Annexes attached to these minutes are as follows; unless expressly stated otherwise, single copies of the documents indicated are attached in the Annexes listed below:

<table>
<thead>
<tr>
<th>Annex No.</th>
<th>Description</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annex 1.4</td>
<td>Excerpt of building encumbrance register</td>
<td>I</td>
</tr>
<tr>
<td>Annex 2.2</td>
<td>Overview of PURCHASE OBJECT 2 / List of items to be transferred subject to sales tax</td>
<td>B</td>
</tr>
<tr>
<td>Annex 9.1</td>
<td>Lease agreement Johannes Gutenberg University Mainz together with addenda No. 1 and No. 2</td>
<td>I</td>
</tr>
<tr>
<td>Annex 10.1</td>
<td>Rental agreement</td>
<td>I</td>
</tr>
<tr>
<td>Annex 12.1</td>
<td>Overview collateral</td>
<td>V</td>
</tr>
<tr>
<td>Annex 13.8.6</td>
<td>Information on contaminated sites</td>
<td>I</td>
</tr>
</tbody>
</table>
Explanation:

The Annexes marked “I” in column 3 of the table do not contain any declarations of intent by the PARTIES. They have been submitted to the parties for their perusal. These annexes are attached to the Deed for informational, explanatory and/or evidentiary purposes.

The Annexes marked “B” in column 3 of the table are inventories / lists within the meaning of section 14 of the German Notarial Recording Act (BeurkG). Reference is made to these Annexes. In accordance with section 14 of the German Notarial Recording Act (BeurkG), the persons appearing waived the reading out of these Annexes. The Annexes were presented to the persons appearing for their information, approved by them and signed by them.

The Annexes marked “V” in column 3 of the table containing explanations by the PARTIES were read out in full.

The NOTARY read these minutes to those present; they were then approved by those present and signed by them and the NOTARY as follows:

/s/ [Signature on behalf of the Seller]

/s/ [Signature on behalf of Buyer 1]

/s/ [Signature on behalf of Buyer 2]
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:

Purchaser’s Employee Incentive Plan
Signing Allocation Schedule
<table>
<thead>
<tr>
<th>Content</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Definitions and interpretation</td>
<td>2</td>
</tr>
<tr>
<td>2. Conditions precedent</td>
<td>25</td>
</tr>
<tr>
<td>3. Sale and purchase</td>
<td>30</td>
</tr>
<tr>
<td>4. Consideration</td>
<td>34</td>
</tr>
<tr>
<td>5. Consideration adjustment</td>
<td>36</td>
</tr>
<tr>
<td>6. Pre Completion obligations</td>
<td>37</td>
</tr>
<tr>
<td>7. Completion</td>
<td>38</td>
</tr>
<tr>
<td>8. Post Completion matters</td>
<td>41</td>
</tr>
<tr>
<td>9. Purchaser’s Employee Incentive Plan</td>
<td>42</td>
</tr>
<tr>
<td>10. Warranties</td>
<td>42</td>
</tr>
<tr>
<td>11. Tax Covenant</td>
<td>42</td>
</tr>
<tr>
<td>12. [***]</td>
<td>42</td>
</tr>
<tr>
<td>13. Purchaser’s remedies</td>
<td>42</td>
</tr>
<tr>
<td>14. Limitations on liability</td>
<td>43</td>
</tr>
<tr>
<td>15. Purchaser’s conduct of Third Party Claims</td>
<td>44</td>
</tr>
<tr>
<td>16. The W&amp;I Policy</td>
<td>45</td>
</tr>
<tr>
<td>17. Protection of goodwill</td>
<td>45</td>
</tr>
<tr>
<td>18. Consideration Shares Lock-up Period</td>
<td>46</td>
</tr>
<tr>
<td>19. General</td>
<td>47</td>
</tr>
<tr>
<td>20. Announcements</td>
<td>53</td>
</tr>
<tr>
<td>21. Costs and expenses</td>
<td>54</td>
</tr>
<tr>
<td>22. Payments</td>
<td>54</td>
</tr>
<tr>
<td>23. Notices</td>
<td>55</td>
</tr>
<tr>
<td>24. Service of Proceedings</td>
<td>56</td>
</tr>
<tr>
<td>25. Sellers’ Representatives</td>
<td>56</td>
</tr>
<tr>
<td>26. Institutional Sellers’ Representative</td>
<td>57</td>
</tr>
<tr>
<td>27. Governing law and jurisdiction</td>
<td>59</td>
</tr>
<tr>
<td>Schedule 1 (The Sellers)</td>
<td>60</td>
</tr>
<tr>
<td>Part 1</td>
<td>60</td>
</tr>
<tr>
<td>(The FME Shareholders)</td>
<td>60</td>
</tr>
<tr>
<td>Part 2</td>
<td>61</td>
</tr>
<tr>
<td>(The Investor Sellers)</td>
<td>61</td>
</tr>
<tr>
<td>Schedule 2 (The Company)</td>
<td>62</td>
</tr>
<tr>
<td>Part 1</td>
<td>62</td>
</tr>
<tr>
<td>(The Company)</td>
<td>62</td>
</tr>
<tr>
<td>Part 2</td>
<td>63</td>
</tr>
<tr>
<td>(The Group Companies (and branches))</td>
<td>63</td>
</tr>
<tr>
<td>Schedule 3 (The Properties)</td>
<td>71</td>
</tr>
<tr>
<td>Schedule 4 (Non-Tax Warranties)</td>
<td>73</td>
</tr>
<tr>
<td>Schedule 5 (Limitations on liability)</td>
<td>98</td>
</tr>
<tr>
<td>Schedule 6 (Tax Schedule)</td>
<td>102</td>
</tr>
<tr>
<td>Part 1</td>
<td>102</td>
</tr>
<tr>
<td>(Definitions and Interpretation)</td>
<td>102</td>
</tr>
<tr>
<td>Part 2</td>
<td>106</td>
</tr>
<tr>
<td>(Tax Warranties)</td>
<td>106</td>
</tr>
<tr>
<td>Part 3</td>
<td>109</td>
</tr>
<tr>
<td>(Covenants to and from the Purchaser)</td>
<td>109</td>
</tr>
<tr>
<td>Part 4</td>
<td>113</td>
</tr>
<tr>
<td>(Limitations and general)</td>
<td>113</td>
</tr>
<tr>
<td>Schedule 7 (Completion obligations)</td>
<td>116</td>
</tr>
<tr>
<td>Part 1</td>
<td>116</td>
</tr>
<tr>
<td>(Sellers’ obligations)</td>
<td>116</td>
</tr>
<tr>
<td>Part 2</td>
<td>118</td>
</tr>
</tbody>
</table>
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 (the “Investor Sellers” and each, an “Investor Seller”);

(together, the “Sellers” and each, a “Seller”):
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


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:

- “SPA” means the Share Purchase Agreement between (1) the Purchasers (as defined therein); (2) InstaDeep; 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 the Paying Agent 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;
(i) 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 next 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 (in a form to be approved by the Purchaser acting reasonably) 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 to be entered into between the Purchaser, The Bank of New York Mellon, as depositary (the “Depositary”) 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 given to it 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.

“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 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 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).
“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 given to it 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/fx-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 columns 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 the 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
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.

“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 [***] 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 given to it 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.

“Independent Expert” means an independent expert whose appointment and terms of reference are governed by sub-clause 19.11 (Independent Expert).

“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.
“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 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 given in clause 18.1.

“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 £0.00001 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" means [***] or such other paying agent as may be agreed between the Purchaser, the FME Shareholders Representative, the Investor Sellers’ Representative and the Institutional Sellers.  

"Paying Agent Agreement" means the agreement in a form reasonably acceptable to the Institutional Sellers, the FME Shareholders Representative, the Investor Sellers’ Representative and the Purchaser.
“Paying Agent Fee” means [***]% of the aggregate amount payable to the Paying Agent 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 agreed form employee incentive plan in respect of the Purchaser’s EIP Amount, 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).

“Purchaser’s Solicitors” means Osborne Clarke LLP of One London Wall, London EC2Y 5EB.
“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 26 (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 (b) 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 Paying Agent’s bank account as shall be notified to the Purchaser by the Paying Agent or the FME (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 person who is or was during the [***] period prior to Completion employed by any Group Company or who was a consultant to any Group Company, and who was so employed or retained by any Group Company in each case whose fees and/or emoluments exceed [***] (or the equivalent amount in local currency in respect of each of the Group Companies) per annum at Completion.

“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 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 22 (Payments), clause 23 (Notices) and clause 27 (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 Claims” 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.


“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.

“[***] Transfers” means:

(a) the call option agreement entered into by the Company, [***] and [***] dated [***] in respect of [***] Ordinary Shares;

(b) the call option agreement entered into by the Company, [***] and [***] dated [***] in respect of [***] Ordinary Shares; and
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 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 laws), 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
the following individuals only in respect of (i) the Non-Tax Warranties at paragraphs 9 to 13 (Employment) and paragraphs 35 to 40 (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 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 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 (Generally 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 22 (Payments);
(j) clause 23 (Notices); and
(k) clause 27 (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
the Minister for Economy having concluded that the Transaction is authorised (with or without condition(s)), or

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 [***] (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;
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 fulfill 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 the [***] 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 the CBT Condition has been satisfied in full (and the provisions of this Agreement shall be deemed to have been amended to give effect to this sub-clause 2.11).

2.12 In the event that the period for satisfying the CBT Condition is extended 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.
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 clause 3.11) 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:

(c) 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);

(d) 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.
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)).

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 the relevant share certificates (or indemnities in lieu of share certificates); and

(ii) the Purchaser shall pay to the FME Shareholder the Consideration (as set out in paragraph (c)) for those FME Retained French Shares.

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), at any time within the period of [***] days commencing one day after the end of the [***] day period referred to in paragraph 3.10(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 Share (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 or by the FME Shareholder on the Purchaser in accordance with paragraph. 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 the relevant share certificates (or indemnities in lieu of share certificates); and
(ii) the Purchaser shall pay to the FME Shareholder the Consideration (as set out in paragraph ) for those FME 2024 French Shares.

(e) If the FME Shareholder fails to comply with paragraph , 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.

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 (the “Applicable Ordinary Shares”). [***] hereby agrees that:
(a) [***] will procure that the 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);
(b) upon the exercise of the Share Purchase Options, [***] will procure that each holder of the Share Purchase Options:
   (i) appoints [***] as their nominee to hold the legal title of the Applicable Ordinary Shares on their behalf under a bare trust; and
   (ii) provides a written direction to [***], as the registered owner of the Applicable Ordinary Shares, to sell the Applicable Ordinary Shares to the Purchaser under the terms of this Agreement; and
(c) [***] will receive the Consideration from the sale of the Applicable Ordinary Shares on behalf of each holder of the Share Purchase Options and as their nominee and will:
   (d) be responsible for paying the Cash Consideration and the Earn-out Consideration for the Applicable Ordinary Shares to each holder of the Share Purchase Options after receipt of the same by [***]; and
   (e) retain the Consideration ADSs as nominee for each holder of the Share Purchase Options and will not transfer the legal title of those Consideration ADSs to each holder of the Share Purchase Options (or as they direct) until after they have been released from the Lock-up Period in accordance with clause 18.
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:

(A) by the payment of a cash sum comprising (i) \([***]\)% of the Sellers’ Upfront Consideration \textit{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 Depositary of the aggregate number of Consideration Shares and delivery by the Depositary 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(c); and

(iii) in respect of the US FME Shareholders, subject to any further adjustments as required to account for any \([***]\) in accordance with this Agreement, by the payment to each US FME Shareholder of the Sellers’ Upfront Consideration \textit{multiplied by} the number of Completion Fully Diluted Shares held by the US FME Shareholders 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 22 (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 Investor Seller pursuant to the terms of this Agreement.
4.4 As soon as practicable (and in any event, within [***] Business Days) 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 an 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) 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.

Subscription monies and Option Tax Liability

4.15 Each FME Shareholder: 35
(a) irrevocably agrees and confirms that they will have delivered to the Company 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 the Paying Agent 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 to the Company (such sums to be applied in accordance with the provisions of clause 4.16).

4.16 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 4.15; 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 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
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 22 (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 22 (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
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 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 Agreement undertakes to enter into the Paying Agent Agreement 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 the Paying Agent for the purposes of this Agreement.

6.9 The Founder Sellers shall, subject to and to the extent permissible by Applicable Law, 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 2.9 (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:

(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) pay in accordance with clause 22 (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; (ii) and (iii) together the “FME Completion Payment”;

(iv) the 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 the Paying Agent shall, in accordance with the Paying Agent Agreement, 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; and
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 (i) the FME Shareholders’ Upfront Cash Completion Payment multiplied by the same number of FME Completion Shares; and (ii) the FME Holdback Amount 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 instruct the Depositary to open depository accounts for each individual Non-US FME Shareholder and 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 those depository accounts.

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) 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;
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

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 the 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
The Purchaser shall, within [***] following Completion, establish the Purchaser’s Employee Incentive Plan, except for the implementation of the share-based aspects, which shall be undertaken within up to [***] following Completion.

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, [***] 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;
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:

- any claim made against it by a third party which may give rise to a Non-Tax Claim; and
- 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:

- 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
- 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:

- consult with the Warrantors as soon as reasonably practicable with regard to the Third Party Claim in question;
- 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;
- 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 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 (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 Senior Employee; 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

45
(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.
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."

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.

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.
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.
(b) Subject to sub-clause 19.4(c) (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(c), 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 effects any rights of the Institutional Sellers, each Institutional Seller; and
(b) the Sellers’ Representatives (excluding the Institutional Sellers’ Representative).
(c) 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.
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’ Representatives) 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.
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.

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.

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.

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.

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.

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.

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.

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 apportioned, 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 [***].

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.
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). 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. Payments

22.1 Save as expressly provided to the contrary in this Agreement:

(a) any payment to be made pursuant to this Agreement by the Purchaser (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 18.2(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.
23. Notices

23.1 Subject to clause 24 (Service of Proceedings), 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) 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.

23.2 Except as referred to in sub-clauses 23.3 (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.

23.3 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.

23.4 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.

23.5 Any notice to be given to the Institutional Sellers (or any one of them) under clause 23.1 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 23).
23.6 A party shall not attempt to prevent or delay the service on it of a notice connected with this Agreement.

24. Service of Proceedings

24.1 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 Seller, 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.

24.2 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.

24.3 [***] 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.

25. Sellers’ Representatives

25.1 Subject to sub-clause 24.1, each of the Sellers (excluding the Institutional Sellers):

(a) 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;
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);

any communication in respect of any matter within the authority of the Sellers’ Representatives (excluding the Institutional Sellers’ Representative) described in this sub-clause 25.1 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 act in the way contemplated by this Agreement and to take any decision as they may decide in their absolute discretion and, provided they act in good faith, 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 omit to do in connection with any matter relating to this Agreement.

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 25.1, 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 23. 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.

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 25.1, 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 23. 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.

26. Institutional Sellers’ Representative

26.1 Each of the Institutional Sellers:

(a) agrees that:
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 26.3 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.

26.2 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 25.1, be valid only if signed by (or on behalf of) all Institutional Sellers and otherwise shall be given in accordance with clause 23. 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.

26.3 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.

27. Governing law and jurisdiction

27.1 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.

27.2 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)

[***]

60
Part 2
(The Investor Sellers)

[***]
(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):
£2,571,256 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
<table>
<thead>
<tr>
<th>Company name</th>
<th>InstaDeep Tunisia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered number</td>
<td>B0187762014, unique identifier: 1347719P</td>
</tr>
<tr>
<td>Date of incorporation</td>
<td>23 April 2014</td>
</tr>
<tr>
<td>Place of incorporation</td>
<td>Tunisia</td>
</tr>
<tr>
<td>Address of registered office</td>
<td>Immeuble ICC3 bloc D 4ème étage, Centre Urbain, Nord Tunis 1082</td>
</tr>
<tr>
<td>Issued share capital</td>
<td>TND 5,000</td>
</tr>
<tr>
<td>Charges</td>
<td>None</td>
</tr>
<tr>
<td>Loan capital</td>
<td>None</td>
</tr>
<tr>
<td>Directors</td>
<td>Zohra Slim (Gérante)</td>
</tr>
<tr>
<td>Secretary</td>
<td>N/A</td>
</tr>
<tr>
<td>Accounting reference date</td>
<td>31 December</td>
</tr>
<tr>
<td>Auditors</td>
<td>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</td>
</tr>
<tr>
<td>Tax residence</td>
<td>Tunisia</td>
</tr>
<tr>
<td>Shareholder(s) at Exchange</td>
<td>499 Shares – the Company</td>
</tr>
<tr>
<td>(Warranted as at the date of this Agreement)</td>
<td>1 share - [***]</td>
</tr>
<tr>
<td>Shareholder(s) at Completion</td>
<td>500 Shares – the Company</td>
</tr>
<tr>
<td><strong>Company name</strong></td>
<td>InstaDeep SAS</td>
</tr>
<tr>
<td>------------------</td>
<td>---------------</td>
</tr>
<tr>
<td><strong>Registered number</strong></td>
<td>842469918 RCS Paris</td>
</tr>
<tr>
<td><strong>Date of incorporation</strong></td>
<td>20 September 2018</td>
</tr>
<tr>
<td><strong>Place of incorporation</strong></td>
<td>France</td>
</tr>
<tr>
<td><strong>Address of registered office</strong></td>
<td>40 bis, rue du Faubourg Poissonnière, 75010 Paris, France</td>
</tr>
<tr>
<td><strong>Issued share capital</strong></td>
<td>€100,000 divided into 100,000 shares of €1.00 each</td>
</tr>
<tr>
<td><strong>Charges</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Loan capital</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Directors</strong></td>
<td>Karim Beguir (Président) and Isabelle Levard (Directrice Général)</td>
</tr>
<tr>
<td><strong>Secretary</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Accounting reference date</strong></td>
<td>31 December</td>
</tr>
<tr>
<td><strong>Auditors</strong></td>
<td>Cabinet Caderas Martin - 43, rue de Liège 75008 Paris</td>
</tr>
<tr>
<td><strong>Tax residence</strong></td>
<td>France</td>
</tr>
<tr>
<td><strong>Shareholder(s)</strong></td>
<td>The Company</td>
</tr>
<tr>
<td><strong>Company name</strong></td>
<td>InstaDeep Nigeria Limited</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>Registered number</td>
<td>1563821</td>
</tr>
<tr>
<td>Date of incorporation</td>
<td>26 February 2019</td>
</tr>
<tr>
<td>Place of incorporation</td>
<td>Lagos, Nigeria</td>
</tr>
<tr>
<td>Address of registered office</td>
<td>7, Ibiyinka Olorub, Victoria Island, Lagos State, Nigeria</td>
</tr>
<tr>
<td>Issued share capital</td>
<td>NGN 10,000,000 divided into 10,000,000 shares of NGN 1 each</td>
</tr>
<tr>
<td>Charges</td>
<td>None</td>
</tr>
<tr>
<td>Loan capital</td>
<td>None</td>
</tr>
<tr>
<td>Directors</td>
<td>Karim Beguir, Zohra Slim, Isabelle Levard</td>
</tr>
<tr>
<td>Secretary</td>
<td>GFS Corporate Services Limited, 5th Floor, NCR Building, 6 Broad Street, Lagos</td>
</tr>
<tr>
<td>Accounting reference date</td>
<td>31 December</td>
</tr>
<tr>
<td>Auditors</td>
<td>Pedabo Audit Services - 67, Norman Williams Street - Ikoyi Lagos</td>
</tr>
<tr>
<td>Tax residence</td>
<td>Nigeria</td>
</tr>
<tr>
<td>Shareholder(s) at Exchange</td>
<td>9,990,000 – the Company</td>
</tr>
<tr>
<td>(Waranted as at the date of this Agreement)</td>
<td>10,000 – [***]</td>
</tr>
<tr>
<td>Shareholder(s) at Completion</td>
<td>9,990,000 shares – the Company</td>
</tr>
<tr>
<td>(Waranted as at Completion)</td>
<td>10,000 shares – InstaDeep SAS</td>
</tr>
<tr>
<td>Company name</td>
<td>InstaDeep South Africa (branch)</td>
</tr>
<tr>
<td>---------------------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>Registered number</td>
<td>2020 / 052350 / 10</td>
</tr>
<tr>
<td>Date of incorporation</td>
<td>29 January 2020</td>
</tr>
<tr>
<td>Place of incorporation</td>
<td>Cape Town, South Africa</td>
</tr>
<tr>
<td>Address of registered office</td>
<td>80 Stand Street, Cape Town 8001, South Africa</td>
</tr>
<tr>
<td>Issued share capital</td>
<td>N/A</td>
</tr>
<tr>
<td>Charges</td>
<td>None</td>
</tr>
<tr>
<td>Loan capital</td>
<td>None</td>
</tr>
<tr>
<td>Directors</td>
<td>Zohra Slim</td>
</tr>
<tr>
<td></td>
<td>Khaled Ben Jilani</td>
</tr>
<tr>
<td></td>
<td>Karim Beguir</td>
</tr>
<tr>
<td></td>
<td>Afif Baccouche</td>
</tr>
<tr>
<td>Secretary</td>
<td>Karim Beguir (InstaDeep Ltd)</td>
</tr>
<tr>
<td>Accounting reference date</td>
<td>31 December</td>
</tr>
<tr>
<td>Auditors</td>
<td>SJ Kruger - PO Box 264 Ferndale 2160</td>
</tr>
<tr>
<td>Tax residence</td>
<td>South Africa</td>
</tr>
<tr>
<td>Shareholder(s)</td>
<td>N/A (branch of the Company)</td>
</tr>
<tr>
<td><strong>Company name</strong></td>
<td>InstaDeep Dubai (branch)</td>
</tr>
<tr>
<td>------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td><strong>Registered number</strong></td>
<td>97028</td>
</tr>
<tr>
<td><strong>Date of incorporation</strong></td>
<td>17 February 2020</td>
</tr>
<tr>
<td><strong>Place of incorporation</strong></td>
<td>United Arab Emirates, Dubai</td>
</tr>
<tr>
<td><strong>Address of registered office</strong></td>
<td>Dubai Internet City, Premises EO 03, Ground Floor building 07, Dubai,</td>
</tr>
<tr>
<td><strong>Issued share capital</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Charges</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Loan capital</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Directors</strong></td>
<td>General manager: Maher Mansour</td>
</tr>
<tr>
<td><strong>Secretary</strong></td>
<td>Karim Beguir (InstaDeep Ltd)</td>
</tr>
<tr>
<td><strong>Accounting reference date</strong></td>
<td>31 December</td>
</tr>
<tr>
<td><strong>Auditors</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Tax residence</strong></td>
<td>United Arab Emirates, Dubai</td>
</tr>
<tr>
<td><strong>Shareholder(s)</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Company name</strong></td>
<td>InstaDeep DE GmbH</td>
</tr>
<tr>
<td>------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td><strong>Registered number</strong></td>
<td>Amtsgericht Berlin (Charlottenburg), HRB 243790</td>
</tr>
<tr>
<td><strong>Date of incorporation</strong></td>
<td>11 May 2022</td>
</tr>
<tr>
<td><strong>Place of incorporation</strong></td>
<td>Berlin, Germany</td>
</tr>
<tr>
<td><strong>Address of registered office</strong></td>
<td>Stresemannstraße 123 - 10963 Berlin</td>
</tr>
<tr>
<td><strong>Issued share capital</strong></td>
<td>€25,000</td>
</tr>
<tr>
<td><strong>Charges</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Loan capital</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Directors</strong></td>
<td>Isabelle Levard (Geschäftsführer)</td>
</tr>
<tr>
<td><strong>Secretary</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Accounting reference date</strong></td>
<td>31 December</td>
</tr>
<tr>
<td><strong>Auditors</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Tax residence</strong></td>
<td>Germany</td>
</tr>
<tr>
<td><strong>Shareholder(s)</strong></td>
<td>25,000 shares of EUR 1.00 each - InstaDeep SAS</td>
</tr>
<tr>
<td>Company name</td>
<td>InstaDeep LLC</td>
</tr>
<tr>
<td>--------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Registered number</td>
<td>37-2045700</td>
</tr>
<tr>
<td>Date of incorporation</td>
<td>11 March 2022</td>
</tr>
<tr>
<td>Place of incorporation</td>
<td>Dover (Delaware)</td>
</tr>
<tr>
<td>Address of registered office</td>
<td>874 Walker Road - Suite C - Dover 19904 (Delaware)</td>
</tr>
<tr>
<td>Issued share capital</td>
<td>$100.00</td>
</tr>
<tr>
<td>Charges</td>
<td>None</td>
</tr>
<tr>
<td>Loan capital</td>
<td>None</td>
</tr>
<tr>
<td>Directors</td>
<td>Karim Beguir</td>
</tr>
<tr>
<td>Secretary</td>
<td>N/A</td>
</tr>
<tr>
<td>Accounting reference date</td>
<td>31 December</td>
</tr>
<tr>
<td>Auditors</td>
<td>N/A</td>
</tr>
<tr>
<td>Tax residence</td>
<td>United States of America</td>
</tr>
<tr>
<td>Shareholder(s)</td>
<td>100 Shares – the Company</td>
</tr>
</tbody>
</table>
Company name: InstaDeep Abu Dhabi (branch)

Registered number: 000007973
Date of incorporation: 29 July 2022
Place of incorporation: Abu Dhabi
Address of registered office: D14-122-049-WeWork Hub71, 14, Al Khatem Tower, Adgm Square, Al Maryah Island, Abu Dhabi, United Arab Emirates

Issued share capital: N/A
Charges: None
Loan capital: None
Directors: General manager: Maher Mansour
Secretary: Karim Beguir (InstaDeep Ltd)
Accounting reference date: 31 December
Auditors: N/A
Tax residence: United Arab Emirates (Abu Dhabi)
Shareholder(s): N/A (branch)
Schedule 3
(The Properties)

[***]

71
Schedule 4
(Non-Tax Warranties)

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 [***].

73
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 124(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.
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
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 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.

16. Insurance

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.

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 £1 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.
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.

(a) 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 provide 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, as far as the Warrantors are aware, sufficient for the operation of the Business as currently conducted.

26.3 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 purport to be held by any Group Company, as a trade secret.

26.4 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 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 or 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.

85
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; (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.
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 Disclosures 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 and 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;
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 déconnexion), the health and safety at work of its employees and workers, and payments of social contributions, immigration, non-discrimination, work of disabled employees, regulations relating to the internal regulations (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 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, customs 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;

95
(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 outgoings 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 (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.
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 23 (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 the 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.
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.


“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.


“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.


“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 Taxation [***] 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.
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.

106
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.
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, in respect of any acquisition, variation or disposal of, or any other Event occurring in relation to, employment-related securities (as defined for the purposes of Part 7A, 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 change 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 whenever 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);
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);

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

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 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 countering 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 the relevant 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.
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 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;
(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 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.
On Completion, the Purchaser shall deliver (or procure the delivery of) to the Sellers (to the extent not provided prior to Completion) the Post-Completion Management Agreement, duly signed by the Purchaser.
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.
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.
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 £200,000,000.

"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,

"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:

[*]

(continued 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 (including [*], 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 [*] 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(c) 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 the Founder Sellers and the Purchaser as 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 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 benchmark 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 £[***]
Executed as a deed by Instadep Ltd

Acting by Karim Beguir, a director and Zohra Slim, a director

/s/ Karim Beguir

/s/ Zohra Slim

Director
Executed as a deed by Biontech SE, a company incorporated in Germany, acting by

RYAN RICHARDSON

/s/ Ryan Richardson
Authorized signatory

JENS HOLSTEIN

/s/ Jens Holstein
Authorized signatory

who, in accordance with the laws of that territory, is acting under the authority of the company.
<table>
<thead>
<tr>
<th>Subsidiary</th>
<th>Jurisdiction of Incorporation</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioNTech BioNTainer Holding GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Cell &amp; Gene Therapies GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Delivery Technologies GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Diagnostics GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Europe GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Idar-Oberstein Services GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Individualized mRNA Manufacturing GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Innovation and Services Marburg GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Innovation GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Innovative Manufacturing Services GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Manufacturing GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Manufacturing Marburg GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Real Estate Adam Opel Straße GmbH &amp; Co. KG</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Real Estate An der Goldgrube 12 GmbH &amp; Co. KG</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Real Estate An der Goldgrube GmbH &amp; Co. KG</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Real Estate Austria GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Real Estate Haus Vier GmbH &amp; Co. KG</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Real Estate Holding GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Real Estate Versorgungs GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>JPT Peptide Technologies GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>NT Security and Services GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>refano GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>BioNTech Australia Pty Ltd</td>
<td>Australia</td>
</tr>
<tr>
<td>BioNTech R&amp;D (Austria) GmbH</td>
<td>Austria</td>
</tr>
<tr>
<td>BioNTech (Shanghai) Pharmaceuticals Co., Ltd</td>
<td>China</td>
</tr>
<tr>
<td>BioNTech USA Holding, LLC</td>
<td>Delaware</td>
</tr>
<tr>
<td>BioNTech Research and Development Inc.</td>
<td>Delaware</td>
</tr>
<tr>
<td>BioNTech US, Inc.</td>
<td>Delaware</td>
</tr>
<tr>
<td>JPT Peptide Technologies, Inc.</td>
<td>Delaware</td>
</tr>
<tr>
<td>Biopharma BioNTech Israel Ltd</td>
<td>Israel</td>
</tr>
<tr>
<td>BioNTech Rwanda Ltd.</td>
<td>Rwanda</td>
</tr>
<tr>
<td>BioNTech Pharmaceuticals Asia Pacific Pte. Ltd.</td>
<td>Singapore</td>
</tr>
<tr>
<td>BioNTech Turkey Tıbbi Ürünler Ve Klinik Araştırma A.Ş.</td>
<td>Turkey</td>
</tr>
<tr>
<td>BioNTech UK Limited</td>
<td>UK</td>
</tr>
</tbody>
</table>
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 27, 2023
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

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 27, 2023
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 2022 (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.

1, 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 27, 2023

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 2022 (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 27, 2023

By: /s/ Jens Holstein

Jens Holstein
Chief Financial Officer
We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form F-3 No. 333-249991) 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,
(3) 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;

of our reports dated March 27, 2023, 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, 2022.

/s/ Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

Cologne, Germany

March 27, 2023